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ROYAL COMMISSION OF INQUIRY INTO CERTAIN DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND RELATED MATTERS.

Hearing held 8th floor 180 Dundas Street West Toronto, Ontario

The Honourable Mr. Justice S.G.M. Grange

P.S.A. Lamek, Q.C.

E.A. Cronk

Thomas Millar

Commissioner

Administrator

Counsel

Associate Counsel

Transcript of evidence for

October 12, 1983

VOLUME 48

OFFICIAL COURT REPORTERS

Angus, Stonehouse & Co. Ltd., 14 Carlton Street, 7th Floor, Toronto, Ontario M5B 1J2

595-1065



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4	Hearing held	d on the 8th Floor,						
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6	day of Octo	ber, 1983.						
7		gen Ne. 1 Nes.						
8	THE HONOURABLE MR. JUST	ICE S.G.M. GRANGE - Commissioner						
9	THOMAS MILLAR	- Administrato						
10	MURRAY R. ELLIOT	- Registrar						
11								
12								
13	APPEARANCES:							
14	P.S.A. LAMEK, Q.C.) E. CRONK	Commission Counsel						
<ul><li>15</li><li>16</li></ul>	T.C. MARSHALL, Q.C.) D. HUNT ) L. CEECHETTO )	Counsel for the Attorney- General and Solicitor General of Ontario (Crown Attorneys						
17	L. CEECRETO	and Coroner's Office)						
18	I.J. ROLAND) M. THOMSON ) R. BATTY )	Counsel for The Hospital for Sick Children						
19	D. YOUNG	Counsel for The Metropolitan						
20		Toronto Police						
21	W.N. ORTVED	Counsel for numerous Doctors at The Hospital for Sick Children						
22	B. SYMES	Counsel for the Registered						
23		Nurses' Association of Ontario and 35 Registered Nurses at The Hospital for Sick Children						
24								

(Cont'd)





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## APPEARANCES: (Continued) 1 Counsel for Susan Nelles -D. BROWN Nurse 2 E. FORSTER Counsel for Phyllis Trayner -3 Nurse J.A. OLAH Counsel for Janet Brownless -4 R.N.A. 5 B. KNAZAN Counsel for Mrs. M. Christie -R.N.A. 6 P. CONNELLY Counsel for Mr. & Mrs. Gosselin, 7 Mr. & Mrs. Gionas, Mr. & Mrs. Inwood, Mr. & Mrs. Turner, and Mr. & Mrs. Lutes (parents of 8 deceased children) 9 F.J. SHANAHAN Counsel for Mr. & Mrs. Dominic Lombardo (parents of deceased 10 child Stephanie Lombardo); and Heather Dawson (mother of deceased child Amber Dawson) 11 W.W. TOBIAS Counsel for Mr. & Mrs. Hines 12 (parents of deceased child Jordan Hines) 13 J. SHINEHOFT Counsel for Lorie Pacsai and 14 Kevin Garnet (parents of deceased child Kevin Pacsai) 15 16 17 VOLUME 48 18 19 20

## INDEX OF WITNESSES

NAME

CUTZ, (Dr.) Ernest, Resumed

Re-Direct Examination by Ms. Cronk
Further Cross-Examination by Mr. Tobias

ELLIS, (Dr.) Graham, Recalled

Direct Examination by Ms. Cronk

654

## INDEX OF EXHIBITS

No.	Description	Page No.
208	Document entitled: "Neonatal Neuropathology Check List."	640
32B,	Tab 45 - Two pages, January 13th and January 14th.	807
20.9	2-page document entitled "Mary's Notes, around 24 March '81".	825

/DM/ak

--- Upon commencing at 10:00 a.m.

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THE COMMISSIONER: Yes, Miss Cronk.

DR. ERNEST CUTZ, Resumed

## RE-DIRECT EXAMINATION BY MS. CRONK:

- $\Omega$ . Good morning, Dr. Cutz.
- A. Good morning.
- Q. Dr. Cutz, do you recall having a discussion with Mr. Scott last Tuesday regarding the samples for digoxin assay that were taken from the body of Janice Estrella?
  - A. Yes, I do.
- $\Omega$ . I would like to be clear, Doctor, as to what your evidence in respect of that matter is.

First, as I understand it, you had absolutely no involvement in the actual performance of the autopsy on Janice Estrella, do I have that correctly?

- A. That is correct, yes.
- Q. You were not there when the blood samples were taken which were later used for digoxin assay, and because you were not there as I understand it you did not observe how and in what manner the samples were actually taken?
  - A. No, I didn't.

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Q. And similarly, Doctor, because you were not there, you did not have an opportunity to observe what the condition of the body was at the time those samples were taken; do I have that correctly?

A. Yes.

Q. And you had no involvement as I understand it in the preparation of the final autopsy report which was later prepared concerning the autopsy on Janice Estrella?

A. Yes, that is correct.

Q. Did you - and because you didn't have any involvement at that stage I take it then that you did not then have the opportunity to discuss with Dr. Taylor the manner in which he had personally obtained those samples from the body of Janice Estrella?

A. No, I did not.

Q. Did you subsequently, after the autopsy had been performed and the final autopsy report prepared, have an opportunity prior to the end of March, 1981 to discuss with Dr. Taylor the manner in which he had obtained those samples and the condition of the body at the time that he obtained them?



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A. No, I did not
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Q. I take it then, Doctor, that you do not know for a fact what was or was not present in the pelvic cavity of Janice Estrella at the time a blood was taken from that source for digoxin assay; is that correct?

A. Yes.

Q. And Doctor, as I understood your previous evidence, you told us that prior to the case of Kevin Pacsai, you had never taken a sample, a blood sample for a postmorten digoxin assay; is that correct?

A. That is correct.

 $\Omega$ . Pacsai was your first

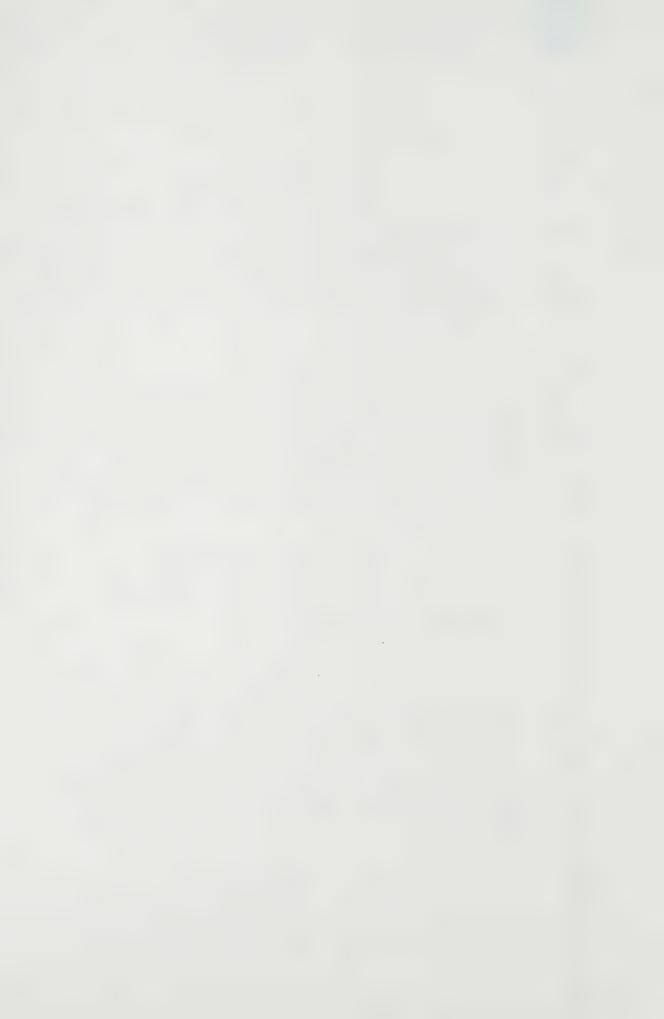
experience in that regard?

A. Yes.

O. And when it came to the case of Kevin Pacsai, as I understood your evidence, you did not milk a leg vein to obtain the sample, but rather you used a syringe to aspirate or to draw the blood directly from the inferior vena cava; is that correct?

A. That's correct.

Q. And similarly when we come to the case of Allana Miller, and we know you had



involvement on that autopsy, you did not I take it observe Dr. Taylor draw a blood specimen by milking a leg vein from that child?

- A. No, we did not.
- $\Omega$ . That sample as well was drawn directly from the inferior vena cava by the use of a syringe and a needle you have told us.
  - A. That is correct.
- O. And when we come to the case of Justin Cook, once again I take it you did not observe Dr. Taylor milking a leg vein in respect of that child to obtain a blood specimen for digoxin assay?
  - A. That is correct.
- Q. Have you in fact, Doctor, ever observed Dr. Taylor milking a leg vein for the purposes of obtaining a blood specimen for a digoxin assay?
  - A. No, I did not.
- Ω. Have you yourself ever had occasion to do so?
  - A. No, I did not.
- $\Omega_{ullet}$  Doctor, as I understood your evidence with respect to your discussion with Mr. Scott, you told him that you were present at





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least	in	part	for	the	evidenc	ce of	Dr.	Taylor	on	his
last	day	here;	do	you	recall	that:	?			

Yes, I was. Α.

0. You would have heard then T take it, you would have heard Dr. Taylor describe the precautions which he took prior to drawing that leg vein sample from the body of Janice Estrella?

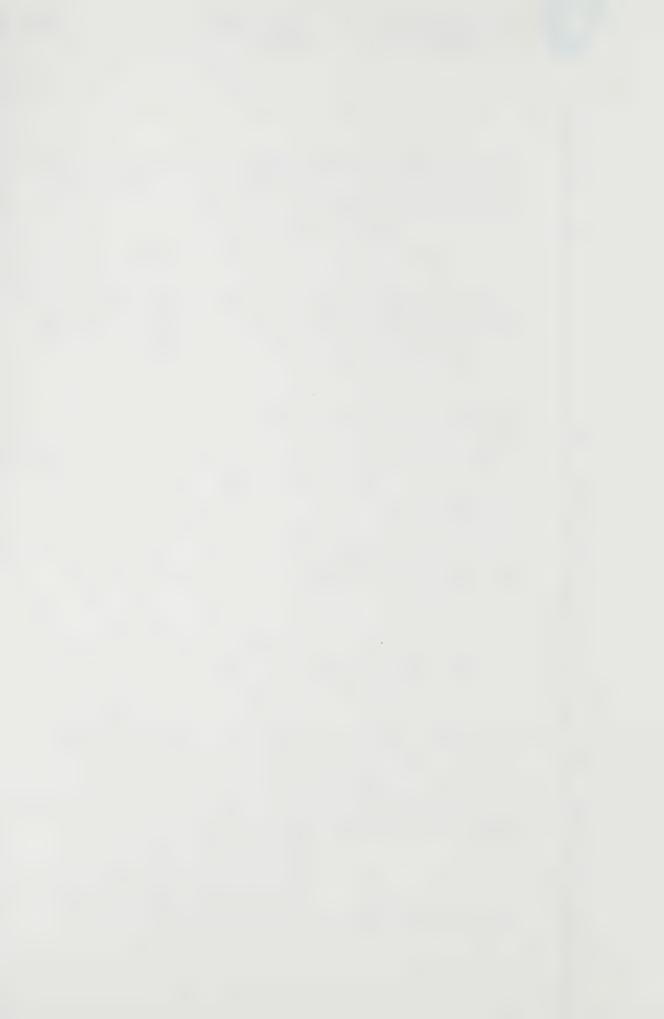
No, I don't believe I was here when he discussed the manner by which he obtained the sample, I think it was some other aspect.

0. All right. Do you recall him talking about, in the sense of precautions that he took, talking about cleaning and drawing the surrounding tissues near the cut by the leg vein; do you recall that?

I recall hearing it, but I am A. not sure whether I heard it here.

Do you have any recollection of hearing Dr. Taylor here in these proceedings indicating that he allowed a few drops of blood to flow out of the vein before he then used a syringe to aspirate blood back into the syringe to take the sample?

- A. Yes, I heard about that.
- Q. Did you also hear Dr. Taylor here in this court room say that he had given



attention to the site from which he could draw a clean sample, and he felt that the leg vein site itself was the only then available site from which he could obtain a clean specimen of blood, did you hear him say that as well?

A. Yes.

Q. You heard him I take it say that he used a syringe and not a collector receptacle of some other kind to obtain that blood specimen; did you hear him say that?

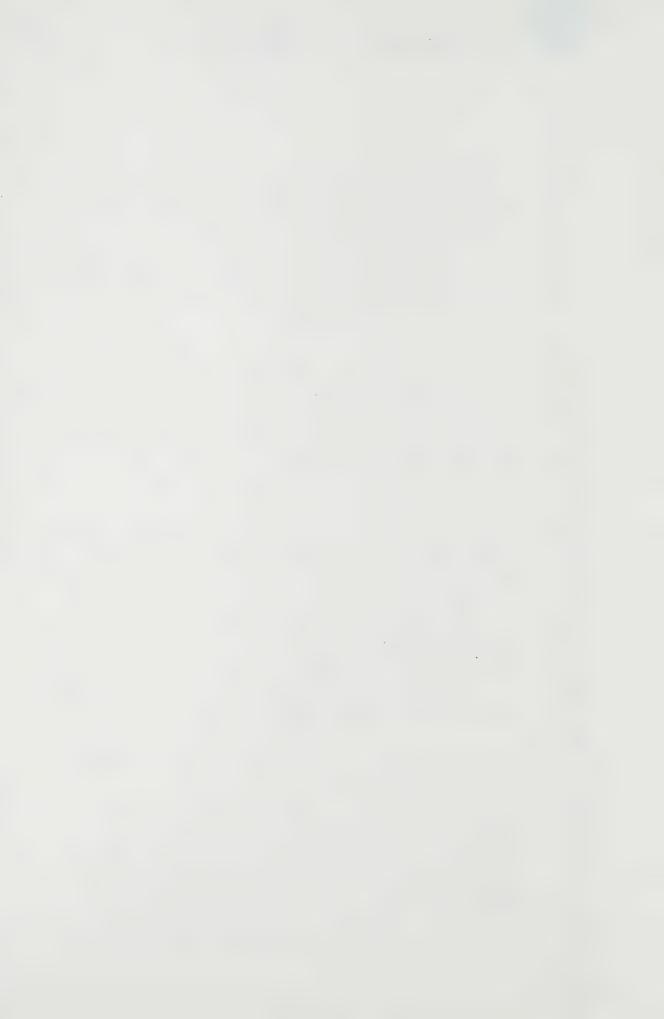
A. He did, yes.

Q. Doctor, you said, as I understood, that in order for Dr. Taylor to obtain blood from the leg vein, these were your words, he had to exert quite a lot of pressure on the leg tissues, perhaps introducing some more edema fluid or fluid from the muscle, possibly causing some contamination; do you recall giving that evidence, Doctor?

A. I can't recall it exactly, it might have come up.

Q. To assist you and the Commissioner that evidence is found in Volume 44, page 9018 and I will ask you to accept for the moment that that is the language that you used.

Doctor, I am curious as to the basis



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upon which you felt that Dr. Taylor had	to exert
quite a lot of pressure on the leg vein	to draw
that sample. I take it that Dr. Taylor	didn't tell
you that; am I correct?	

Α. No.

Q. And I take it you didn't hear Dr. Taylor say that in this court room?

I heard Dr. Mancer at some other point describing it. I am not sure whether I heard Dr. Taylor, at what stage I came in I can't recall.

Q. Do you have any recollection of hearing Dr. Taylor, the person who drew the sample, describe the way he drew the sample by saying he had to exert a great deal of pressure on those muscles in the leg to draw the blood, did you hear Dr. Taylor say that?

I heard the discussion but I am not certain it was from Dr. Taylor.

0. What I am suggesting to you, Doctor, ---

THE COMMISSIONER: Just a moment. Miss Cronk.

MR. ROLAND: Mr. Commissioner, as I recall the evidence, and I may be wrong in this,



it is my recollection is it wasn't Dr. Taylor that milked the leg vein, with his hand on the leg, it was Dr. Gillan who was with him and Dr. Taylor was drawing the sample. So to put to the witness how much pressure Dr. Taylor exerted is not ---

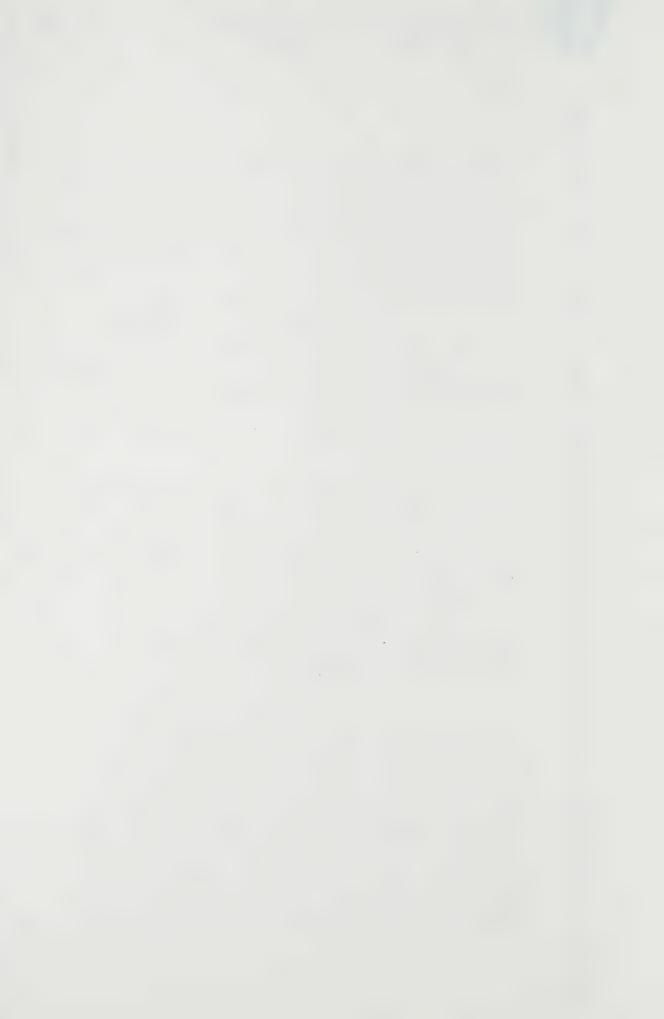
THE COMMISSIONER: I remember

Dr. Gillan held the leg up, whether he also applied the pressure or not I don't know.

MR. ROLAND: I think that was the evidence.

MS. CRONK: It was only in light that may indeed be correct. Certainly the evidence
to date is that those two doctors in concert obtained
that sample. I had understood Dr. Cutz to say that
Dr. Taylor had applied a considerable amount of
pressure to do so. I am simply exploring the basis
of the Doctor's information in making that statement.

Doctor, I am suggesting to you that unless you had a discussion either with Dr. Taylor or Dr. Gillan at which time either explained to you the exact method used by them to draw that sample, that your suggestion that they did not easily obtain the sample but rather had to exert a great deal of pressure, or indeed any pressure at all, is really an assumption on your part?

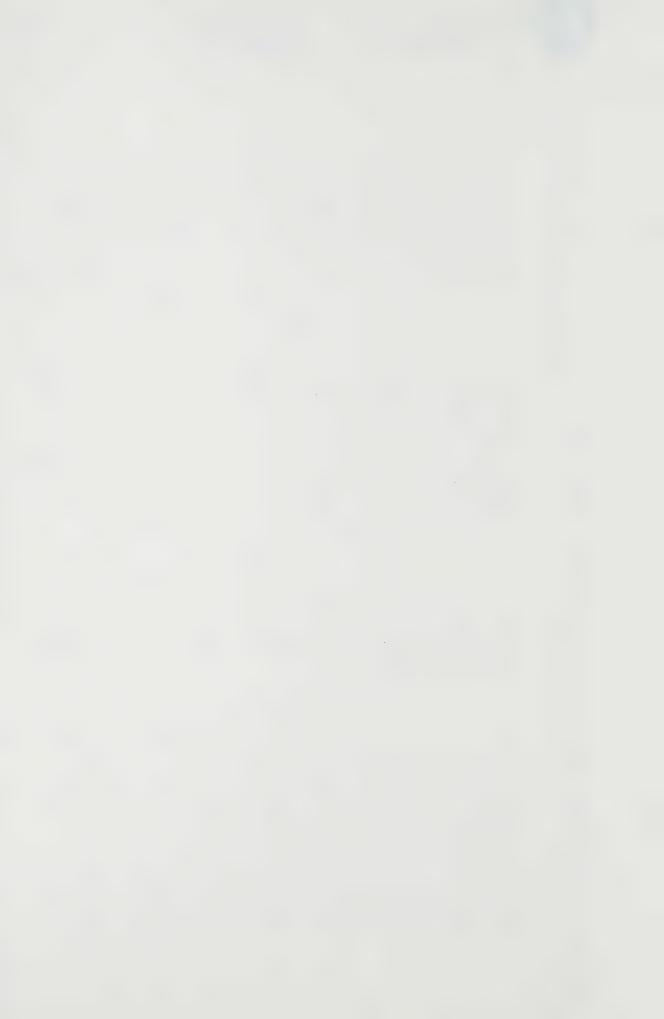




	A. Yes, it is an	assumption, I
assume	e that the question which was	put to me was
to get	t my opinion on the matter rath	er than comment
on the	e facts, which obviously I have	not been present.

- Q. I understand, Doctor.
- A. Yes.
- Q. And because you assumed that that was that the sample was not easily obtained and the pressure had to be exerted to obtain it, it was on that basis, on that basis of that assumption that you said that perhaps some edema fluid or fluid from the muscles might have been introduced?
  - A. That's correct.
- Q. And as we indicated because you were not there you do not in fact know whether in fact edema fluid or muscle tissue was introduced into the sample?
  - A. That is correct.
- Q. Doctor, with respect to the reading itself that was obtained on the leg vein sample. You were asked during the course of cross-examination by Mr. Scott about the level itself.

  You were asked as I understood it what you would have done to pursue that level further, assuming it was not possible to further dilute the sample. We are



talking now about the leg vein sample that resulted in a reading of greater than 4.7 nanograms?

A. Yes.

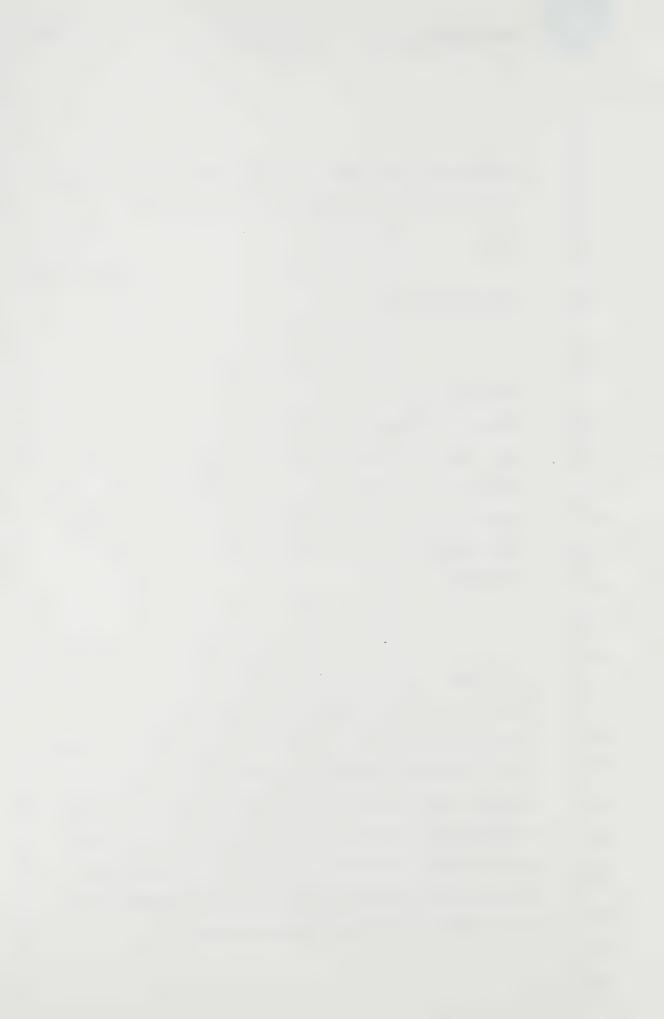
 $\Omega$ . Do you recall Mr. Scott asking you that question?

A. Yes, I do.

Q. And in that regard, as I understood your evidence, Doctor, you indicated a number of things. Firstly you indicated that if you were unable to explain the level you might wish to speak to the clinicians on the assumption that they would know more about digoxin levels than perhaps the pathologists involved would, do I have that correctly?

A. Yes.

Ω. Doctor, it is my understanding that when a level of greater than 4.7 nanograms is recorded by the Biochemistry Department at the Hospital in respect of the digoxin assay, that means that the digoxin concentration in the sample is greater than the maximum which can be measured without further dilution on the assay or the RIA test; and to know the exact level further dilution is required and the sample must be re-assayed. Does that accord with your understanding?





TORONTO, ONTARIO

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Q. In those circumstances, Doctor, would you agree with me that if the sample could not be diluted further, and the first and only reading was simply off the maximum that the assay test was able to produce, we cannot with certainty know what the level in fact was; would you agree with that?

A. Yes, you cannot be absolutely certain but in other cases it may give some other initial readings as I remember in the Pacsai case, the pre-mortem level was even greater than 10.

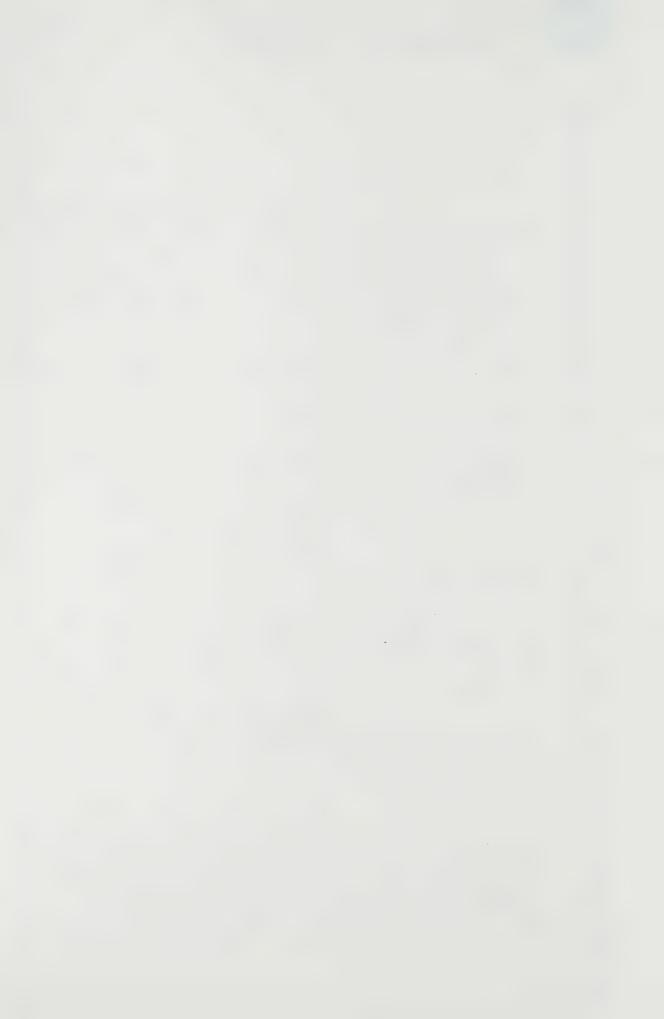
Q. Yes, Doctor.

A. And there are some other examples where it cannot be diluted. So I am not sure, you know, how much importance one can put to the first reading and what is expected once you dilute it.

 $\Omega$ . Doctor, I'm not asking you at the moment for the significance which you place or attach to that level.

A. Yes.

O. My question, or my suggestion to you merely was that without further dilution and without further assay, it is not possible to say what that level in fact was, how much higher it was



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than	4.7;	would	you	agree	with	that,	Doctor?
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A. Yes, I would.

 $\Omega$ . And you have drawn my attention to the Pacsai case?

A. Yes.

Q. Let's talk about that for a moment if we may. Doctor, we know of course that you performed that autopsy and you have familiarity both with the antemortem level and with the postmortem level that was recorded for Kevin Pacsai, correct?

- A. Yes, this is later on.
- Q. Yes, later on, right.
- A. Yes.
- O. Doctor, were you aware in respect of Kevin Pacsai 26 nanograms postmortem level that Dr. Ellis' Digoxin books maintained in the biochemistry laboratory suggest that the first time that sample was assayed a result of greater than 4.8 was obtained?
- A. No, I am not familiar with that, no.
- Q. Were you aware, Doctor, that the entries in those books suggest that after it was assayed first it had to be diluted; it was re-assayed and a level of 24 nanograms was achieved;



were you aware of that?

A. No, I am not, no.

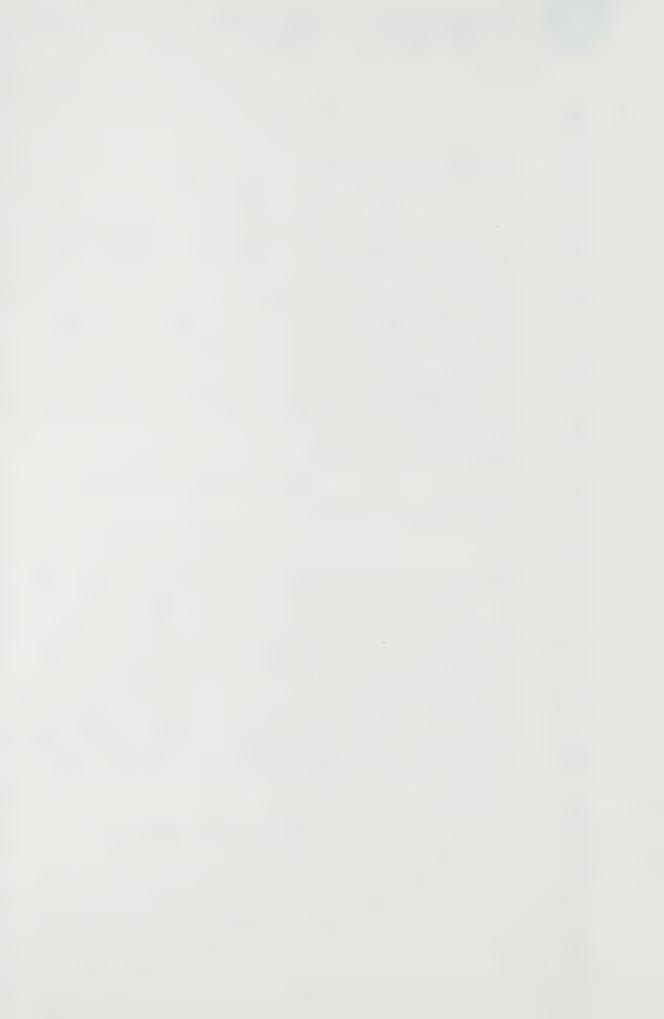
Q. Were you aware, Doctor, that it was diluted and re-assayed again, at least that would appear to be the case from the Digoxin books; and we will hear from Dr. Ellis. On that further dilution, on further assay it resulted in a level of 25.5 nanograms. Then it was diluted again and re-assayed again and that is when the level of 26 nanograms was achieved?

A. No, I was only told about the final reading as being 26.

Q. I understand, Doctor.

Similarly in the case of Allana Miller we know that you supervised that autopsy and Dr. Taylor drew samples that were ultimately tested post mortem for digoxin assay; were you aware in the case of Allana Miller the entries in Dr. Ellis' Digoxin Assay books suggests that on the first assay run the postmortem sample resulted merely in a level of greater than 5 nanograms?

A. No, I did not know.





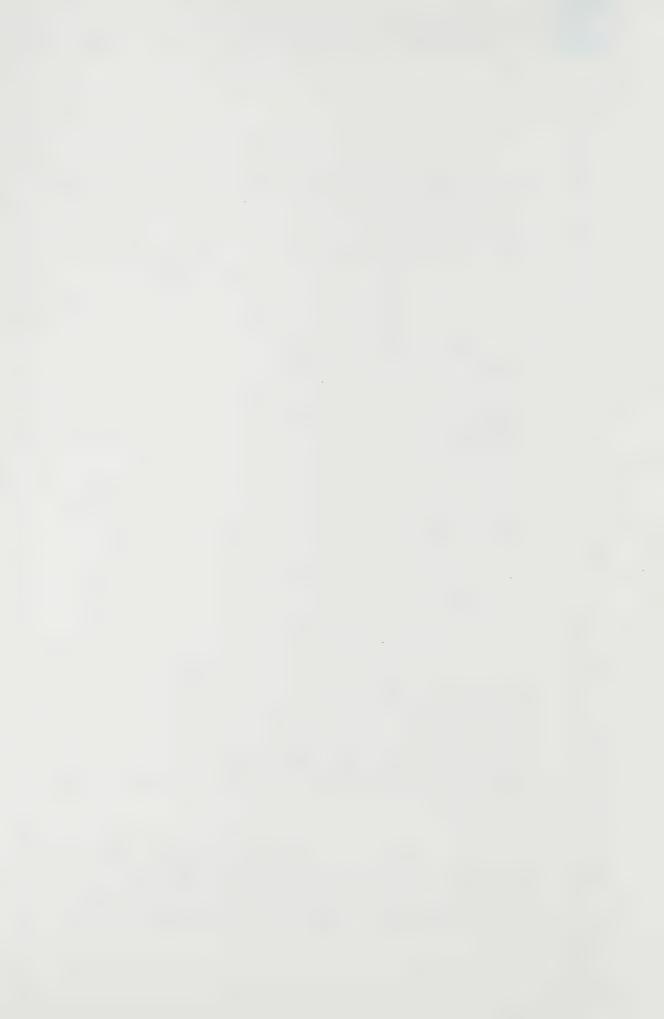
B BB/cr Q. All right. Were you aware,
Doctor, that several dilutions, in fact three, appear
to have taken place before a level of 78 nanograms
was achieved on that sample of Allana Miller?

A. No, I didn't know.

Doctor, if that be so, if in the case of Kevin Pacsai the first reading was merely greater 4.8 and in fact the ultimate fixed reading was 26 and if in the case of Allana Miller the first reading was greater than 5 and the ultimate fixed reading was 78, with those two cases in mind, I take it we can agree that we cannot reasonably assume that a greater than 4.7 level in the case of Janice Estrella would result in a fixed level of less than 10 as you suggested. We can't reasonably assume that, can we, Doctor?

A. Yes. No, I based that comment on the fact that, you know, we had these various dilutions showing different levels at the final reading but, you know, unless you have the diluted final reading you cannot be certain what the actual level is.

Q. Thank you, Doctor. One other point with respect to the Estrella sample. You will recall that I suggested to you that Mr. Scott



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had inquired of you what you would have done if you
had obtained that level and you wished to investigate
the matter further and I suggested to you that your
response was that you said that if you couldn't explain
it, you could perhaps talk to the clinicians on the
assumption that they would probably be more knowledgeable
about the levels of digoxin than the involved
pathologist was. Do you recall that evidence?
7) ***

Yes.

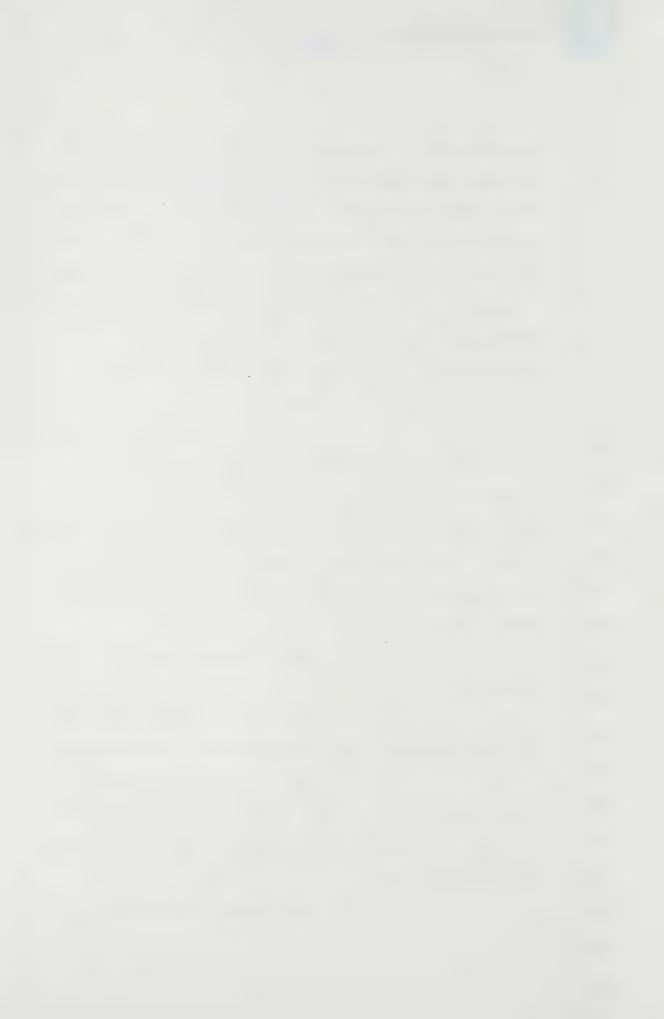
All right. We know that your own experience, your own first experience with a postmortem digoxin level was in the case of Kevin Pacsai and in that case, as I understood your evidence, when you were informed of the level of 26 nanograms you discussed the matter with Dr. Costigan on March 18th, is that correct?

A. Yes, I was told by Dr. Costigan.

Q. All right. And in the course of that discussion you reviewed with him the level?

No. I had only a brief discussion where he told me what the finding was but I can't recall as to what detail we went into as to the interpretation.

> 0. All right. And further on





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March 18th you discussed the matter of that level with Dr. Fowler, as I understood your evidence?

Well, this again was just a brief encounter and we have not concentrated on a discussion about the level itself. But as I understood the purpose of Dr. Fowler's visit was to obtain and review the chart which was in my possession at the time.

> All right. And you saw Dr. Q.

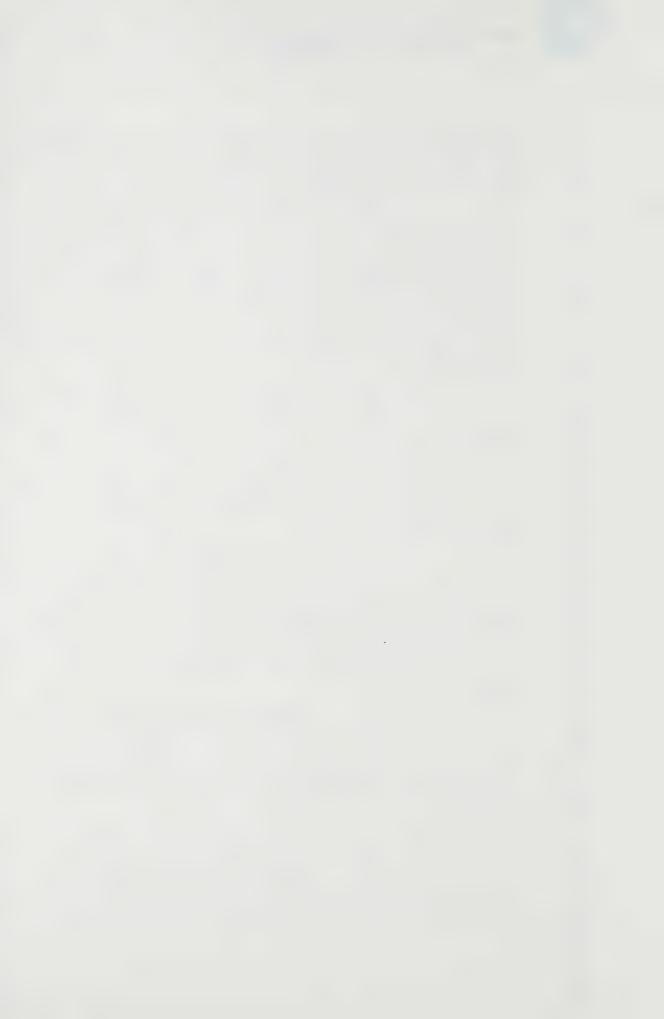
Fowler?

- Α. Yes.
- Q . And provided the chart to him

on the 18th?

TORONTO, ONTARIO

- Α. That's right.
- And that was because of the Pacsai level that had been obtained and you thought, you knew that that was why he was looking at the chart?
  - Α. That is correct, yes.
- Q. All right. And also on March 18th, you did discuss it with Dr. Ellis, you have told us?
  - A. That is correct.
- Q. And that conversation was a more detailed one than the other two that you have



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just described?

A. Yes. That was more - I think

Dr. Ellis came to see me to enquire about that sample.

Q. All right. And you had a

discussion with him?

A. Yes.

Q . As to the level?

A. Yes.

Q. And as I recall with respect to whether or not any tissue samples were available and you discussed how that level might have been achieved?

A. That's correct, yes.

Q. Do I have that correctly?

A. Yes.

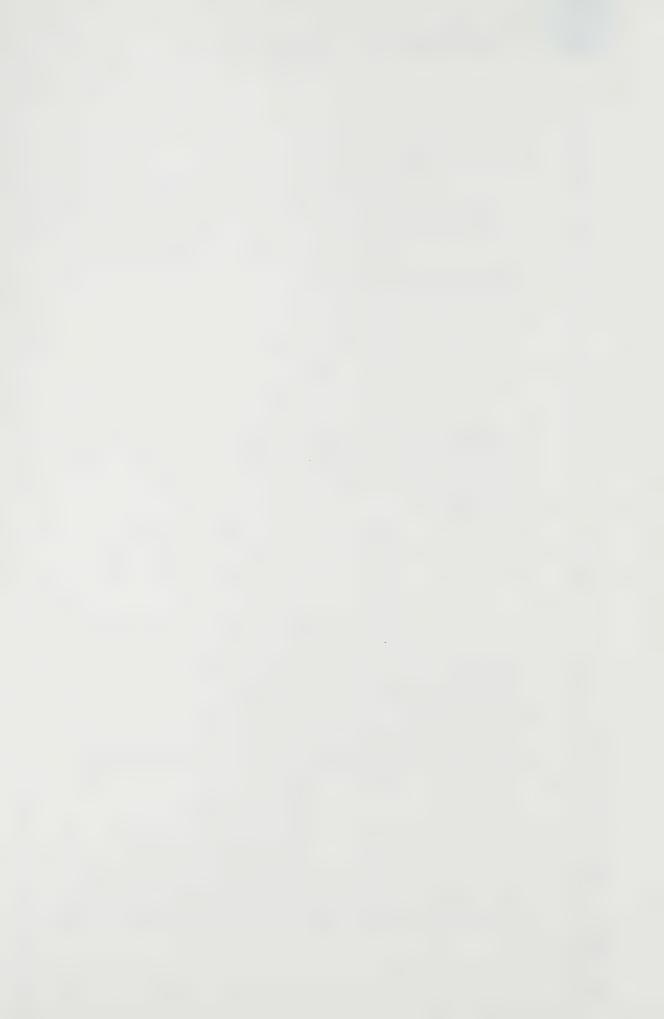
Q. All right. And then as I understood it, after discussing the matter with those three individuals on March 18th you sought out Dr. Mancer on March 20th for the specific purpose of obtaining his input with respect to that level?

A. Yes.

Q. Am I correct?

A. That's correct, yes.

Q. So that in respect of the Kevin Pacsai level about which you had been informed

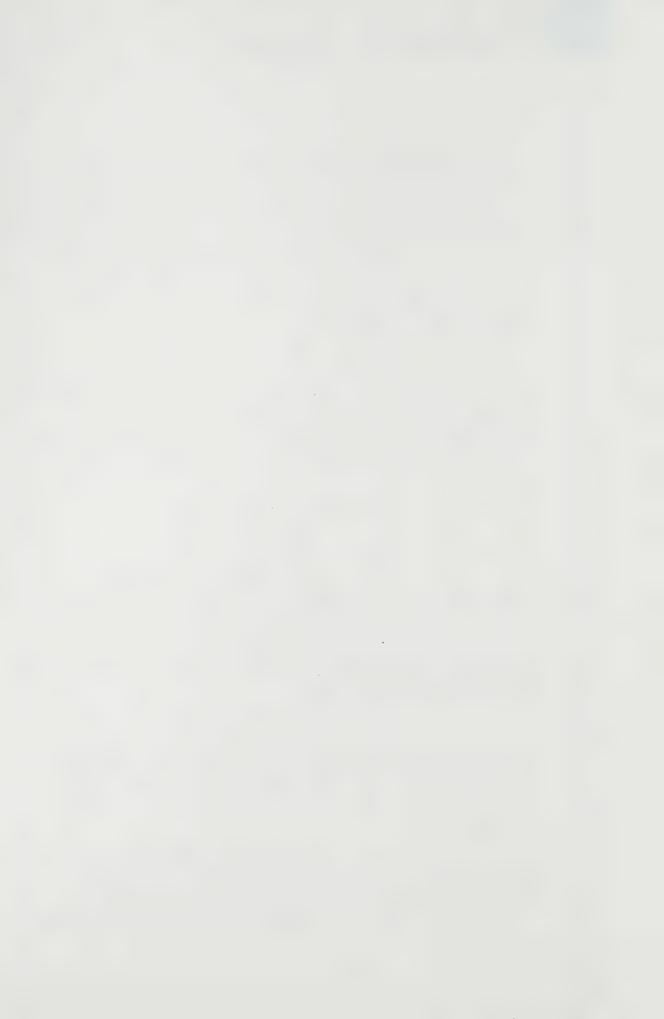


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it was raised in discussions that you held with Dr. Fowler, Dr. Costigan, Dr. Ellis and Dr. Mancer either on the 18th of March or on the 20th of March?

- A. Could you rephrase it, please.
- Q. In respect of that Pacsai level, the 26 nanograms.
  - A. Yes.
- Q. That was a matter of discussion between yourself and Dr. Costigan, Dr. Fowler, Dr. Ellis and Dr. Mancer on March 18th and on March 20th.
  - A. Yes.
  - Q. Is that correct?
  - A. Yes, yes.
- Q. All right. Doctor, as I understood your evidence with Mr. Scott you suggested that you had also discussed the matter with Dr. MacLeod of the Pharmacology Department at the Hospital. Do I have that correctly?
- A. Yes. I discussed it, I can't recollect the exact time but we certainly discussed it either after the 25th, probably after the 25th of March.
- Q. That was my next question, Doctor, when you discussed it with Dr. MacLeod?
  - A. I can't recall that that would

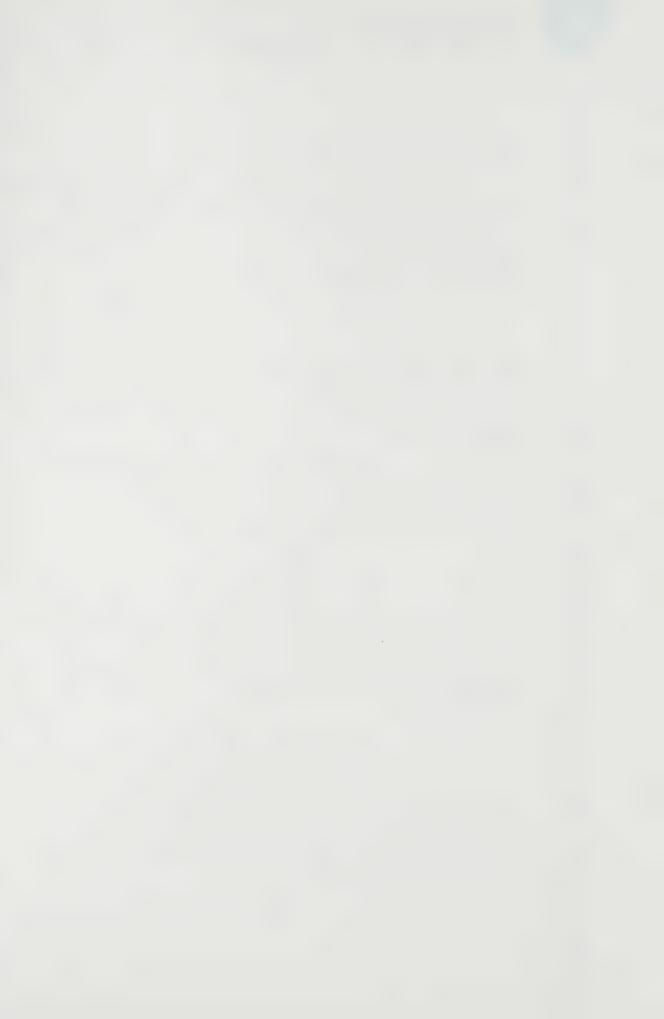


have been prior to the 26th of March.

- Q. All right. And I take it then at that time it was discussed by Dr. MacLeod and yourself in the context of the events that had taken place over the weekend of March 21st?
  - A. That is correct, yes.
- Q. All right. Doctor, I would like to draw your attention now to Exhibit 198. Mr. Registrar, perhaps if you could show the Doctor a copy of that.

Doctor, as I understood your evidence with respect to this exhibit, specifically the column entitled Cause of Death.

- A. Yes.
- Q. You told me, as I understood it, that the information contained in those columns was based on the findings detailed in the autopsy reports of the individual cases. Do I have that correctly?
  - A. Yes, that is correct.
- Q. All right. And you also told me, as I understood it, that the autopsy reports included the microscopic examination results. Do I have that correctly?
  - A. Yes.



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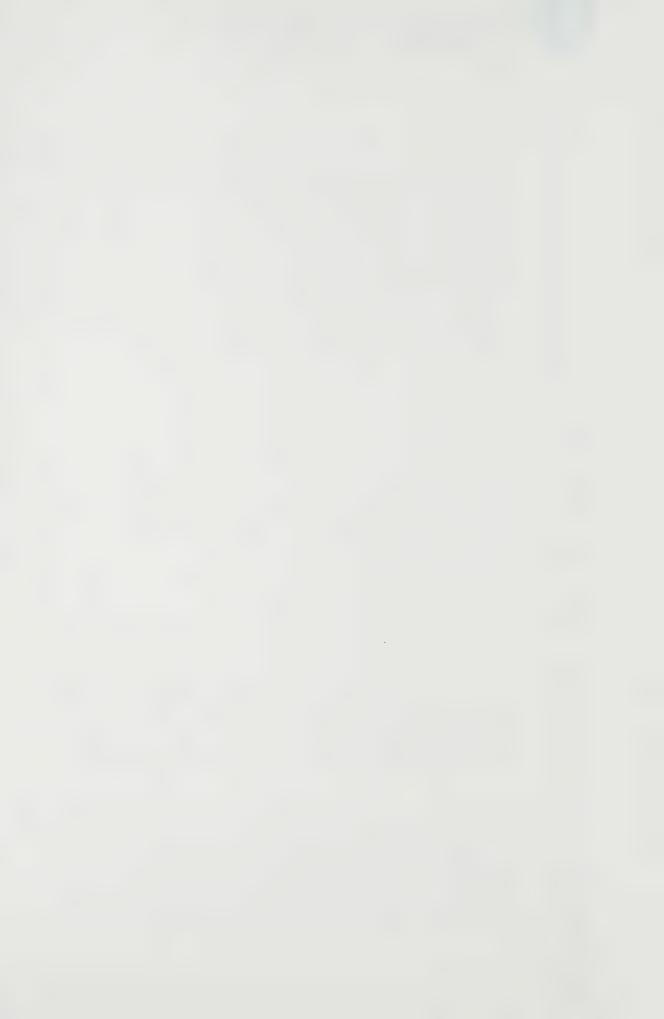
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0. All right. And as I understood it, in cross-examination and discussion with Mr. Scott you indicated that the actual autopsy reports, including the pathological discussion sections of those reports were prepared between 11:00 a.m. on Tuesday March 24th and 10:00 a.m. on Wednesday, March 25th. Do I have that correctly?

- Α. Yes.
- 0. 1981?
- Α. Yes.
- 0. All right. In the case of Kevin Pacsai your attention was drawn by Mr. Scott to the document that is entitled Preliminary Autopsy Report?
  - A. Yes.
  - Q. Do you recall that?
  - Α. Yes.
- 0. And your evidence in that regard with that report was really nothing more than your personal notes. Do I have that correctly?
  - A. Yes.
- All right. Doctor, in respect of that document, I take it and you have told us previously that it is not the normal practice in a coroner's case for a preliminary autopsy report



## ANGUS. STONEHOUSE & CO. LTD. Cutz, re.dr. (Cronk)

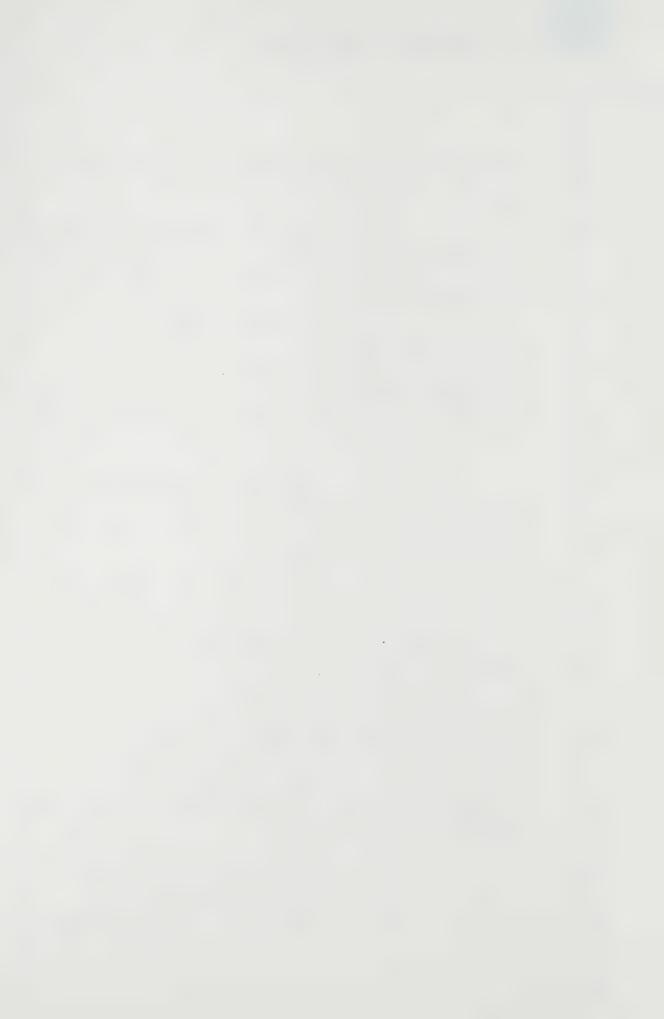
so-called to be prepared at the Hospital. Is that correct?

- A. Well, it would be prepared but it would not be distributed. In other words, it would not leave my office.
- Q. Is it then, Doctor, in a coroner's case your normal practice to prepare a preliminary autopsy report as well as the report of the postmortem examination that goes to the coroner?
- Q. All right. And for what purpose do you prepare those preliminary autopsy reports in coroner's cases?

Yes.

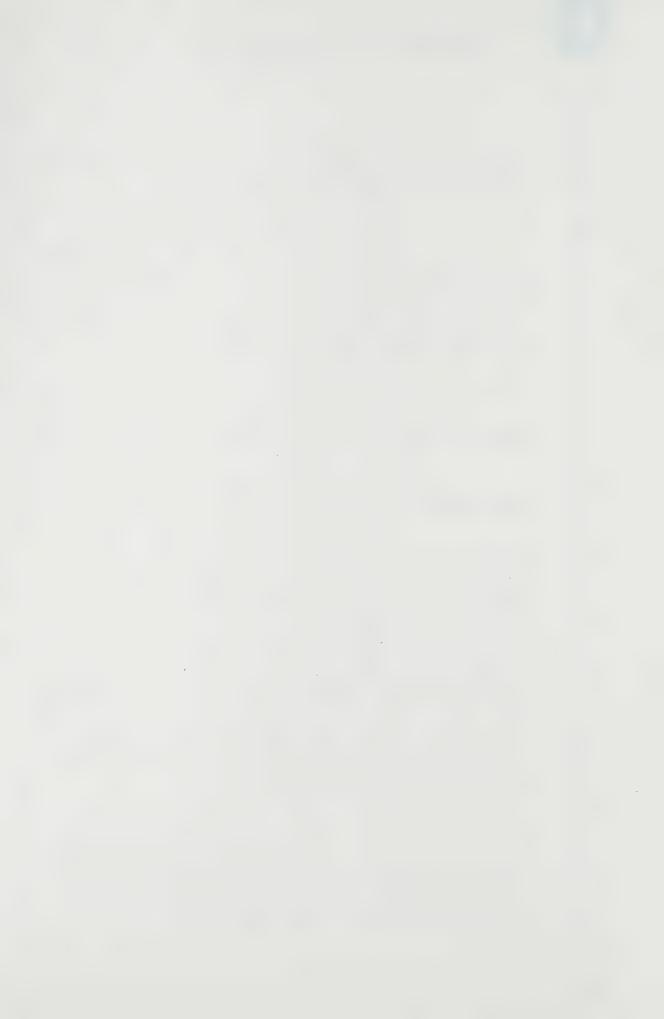
A. Well, it is for my own personal use when the final report is signed out so I can refresh my memory two months later what the problems were and put it into the context, you know, what the findings were then and what they are after all these things are completed. So, it is for my personal use and it may also be used by the neuropathologists when they examine the brain so they know what the case is about.

- Q. Someone such as Dr. Becker?
- A. Such as Dr. Becker, yes.
- Q. All right. And is that report,



the prelimi	lnar	ry ar	ıtopsy	repo	ort	that	you	would	prepare
maintained	in	the	Pathol	Logy	Dep	artme	ent?		

- A. That is correct, yes.
- Q. All right. And is that copy that is maintained in the Pathology Department then available for other members of the Pathology Department to review should they wish to do so?
  - A. Yes.
- Q. All right. And was that the case with respect to this preliminary autopsy report?
- A. Well, it was for basically the same purpose but it would not leave the Department.
- Q. All right. I take it then,
  Doctor, that because it was prepared for your own
  future reference at the time of signing out the
  final autopsy report and as well for the purposes
  of being available to other colleagues such as Dr.
  Becker and other members of the Pathology Department
  that that is why it is typed up in the form in which
  we see this one and your signature appears formally
  on the bottom of the report?
  - A. That is correct, yes.
- Q. All right. If it was simply your own personal notes I take it that that degree of formality might not be required?



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	Α.	Well	, it is	not	really a	degree
of formality.	The	signature	e means	that	t I have	
prepared it an	dII	nave seen	it.			

- 0. All right.
- A. Since it's typed.
- 0. All right. And in the normal case, as I understand it, Doctor, as you have explained it, there would be an interval of time elapsed between the date of your signing the preliminary autopsy report and the date of preparing and finalizing the final autopsy report. Do I have that correct?
  - Α. Yes.
- So that the preliminary autopsy report, even in a coroner's case, serves as a useful tool for you to refresh your memory when it comes time to complete and finalize the final autopsy report?
  - Α. That is correct, yes.
- Q. All right. Now, Doctor, as I understood your evidence you were asked when, in the case of Kevin Pacsai, the preliminary autopsy report was prepared and I had understood your evidence to be that you had thought that it was at the same time as the final autopsy report, that is, in the latter



part of Tuesday, March 24th or the early part of Wednesday, March 25th. Is that your evidence in that regard?

A. Yes.

Q. All right. Do you have any recollection one way or another, Doctor, as to when this preliminary autopsy report was prepared?

A. I do not know the exact date or I can't recall exactly but I could not have made it before the 18th because I didn't know the results.

Q. All right.

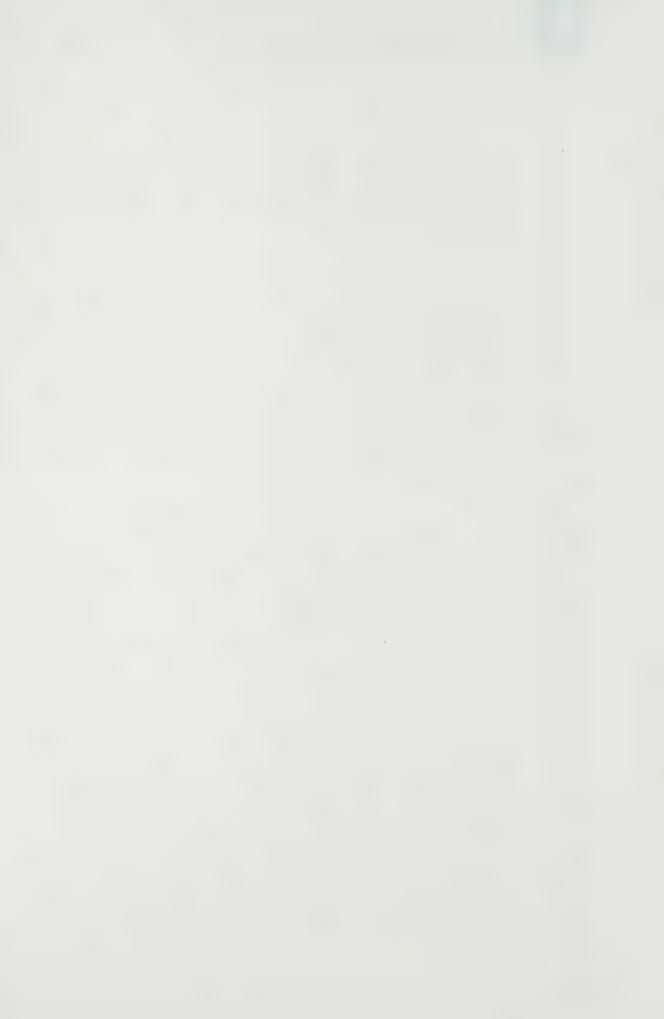
A. And after the 18th the things went fast, I had other things to worry about. So, I'm almost sure that I could not make, did not make that report before Monday.

Q. All right. My only curiosity arises - Monday, March 23rd?

A. Yes.

Q. All right. My only curiosity arises with respect to the date, Doctor, for this reason. As I have understood your evidence, Dr.

Mancer and yourself were hard pressed, under considerable time pressures to complete all of the final autopsy reports that you in fact had been requested to complete the evening of March 24th and the afternoon



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of March 24th and the morning of March 25th?

Α. Yes.

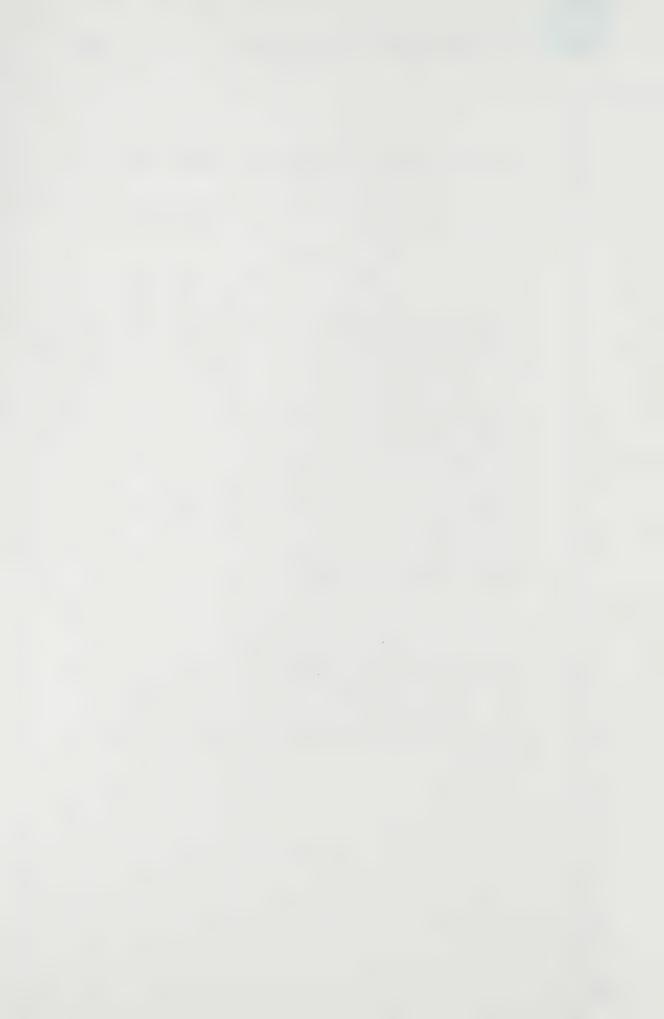
Do I have that correct? 0.

Α. Yes.

And given those time

constraints and given that you had 10 final autopsy reports to prepare, I found it curious that you would also take it upon yourself at that stage to prepare a preliminary autopsy report for Kevin Pacsai instead of going directly to the final. My suggestion to you is, that given your evidence with respect to the climate of those two days when you were preparing those reports, that it is likely that this preliminary autopsy report was prepared prior to March 24th?

No. I can maybe explain it on the fact that when actually the so-called preliminary report was prepared it has several notes on it saying that brain has not been examined I believe and that the conduction system was not examined.





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And at the time this report was prepared the heart was already seized, or the heart tissue that we had was already seized, so that because these other studies were not completed yet and since this report was in this circumstance was more intended to give information for the investigation --

Q. Did that apply, Doctor, both to the preliminary autopsy report and the final one?

A. No, the final report was written - it would be written on April 20th or so.

Q. Are you saying that --

A. It was prepared the same time the coroner's report was prepared, and copy of the final report on the Hospital stationery would just go into the books within the department.

Q. All right. Doctor, I would like to be clear on this.

A. Yes.

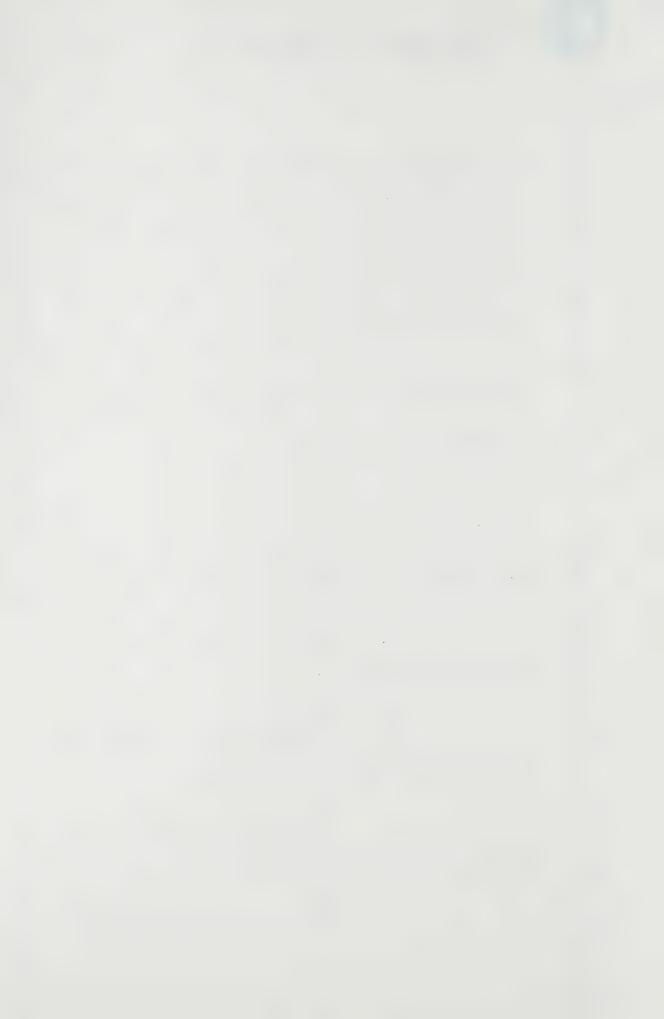
Q. I am showing you a copy of the final autopsy report which is Exhibit 106A.

A. Yes.

Q. I am showing you as well a copy of the preliminary autopsy report.

A. Yes.

Q. Is it your evidence that the





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final autopsy report was not prepared on March 24th and March 25th and was delivered and was available to the police but rather only the preliminary autopsy report?

> A. Yes.

0. Thank you.

the report then which came into the possession of the Metropolitan Toronto Police as a result of your efforts and those of Dr. Mancer in those two days is the preliminary autopsy report?

That is correct.

And I take it we can agree, Doctor, that the conclusion reached in that report is the same as the conclusion reached by you in the final report which you ultimately signed, and that is that the immediate cause of death was digitalis toxicity?

Yes, that is correct.

Am I correct in that regard?

I take it we can agree, Doctor, that whether or not the Metropolitan Toronto Police had become involved at the Hospital, their involvement one way or another doesn't affect the fact that a postmortem digoxin level of 26 nanograms was reported in this case?



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A. That is correct.

Q. All right. You told Mr. Scott as I understood it that that level of 26 nanograms was a level that you could not explain on the basis of the pathological and clinical findings in this case?

A. That is correct, yes.

Q. Do I have that correctly, Doctor?

A. Yes.

Q. I suggest to you, Doctor, in those circumstances whatever else happened that level could not be ignored by you and indeed it wasn't, and it was on the basis of that level that you concluded this child died of digitalis toxicity?

A. Yes.

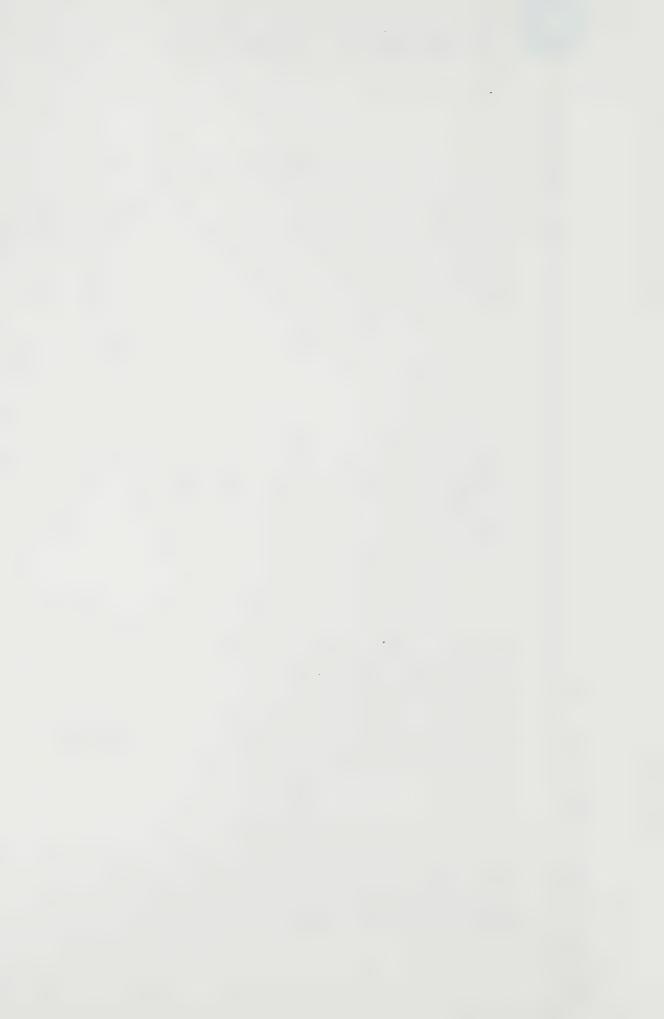
Q. All right. And whether or not the police were there on March 23rd or April 23rd or May 23rd that was a level that you as a pathologist could not have ignored given your concerns about it, and it would have led you to the conclusion that this child died of digitalis toxicity?

A. Yes.

Q. All right.

Doctor, you were asked as well by Mr.

Scott why the post mortem level had been ordered for digoxin in respect to Kevin Pacsai, and as I understood





your evidence yesterday it was suggested to you by Mr. Scott, and you agreed, that the medical chart had directed your attention to digoxin in this case. Do you recall that?

A. Yes.

Q. And Mr. Scott suggested to you that it was Dr. Costigan's two notes on the chart which led you to order that level?

A. Yes.

Q. Do you recall that?

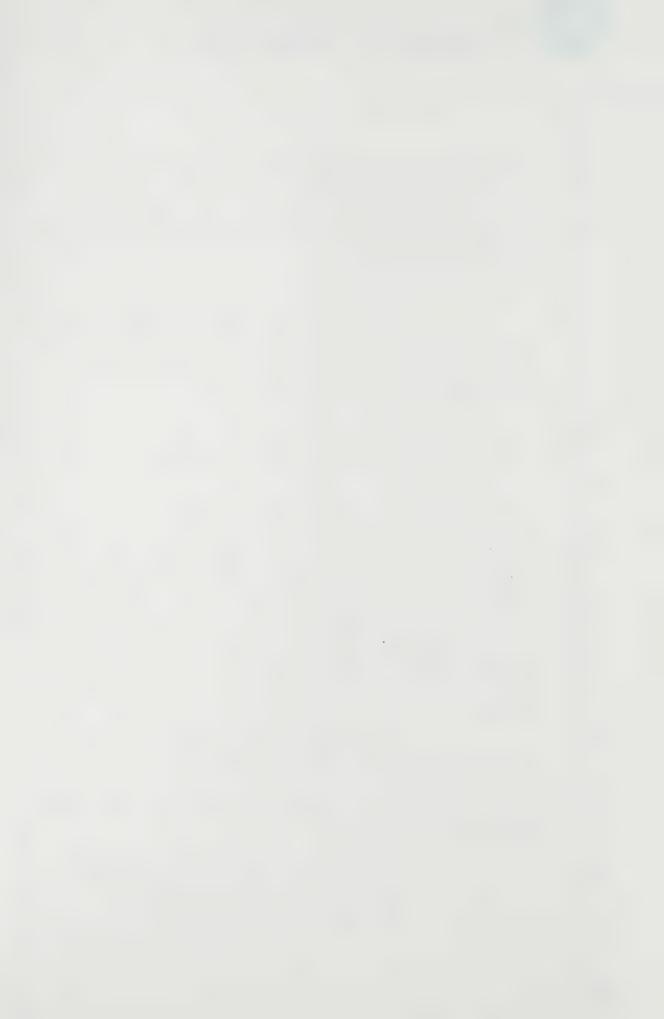
A. Yes.

Q. All right. Doctor, you may recall during our discussion in chief that I as well asked you why you had ordered that postmortem digoxin level, and I had understood your answer to be perhaps a little different than the one that was offered yesterday and I would like simply to refresh your memory.

It appears at Volume 42, page 8543
I asked you who had ordered the digoxin level in the
Pacsai case, and you told me that you had, and I then
asked you this question:

"All right. Can you tell me, Doctor, why in this case you did that?

"A. Well, as I mentioned, I try to do





"a thorough autopsy covering the various possibilities and this appeared as one possibility. So that was the only reason to actually do it.

"Q Prior to this case, Doctor, had you ever had occasion during any other autopsy that you conducted at the Hospital to order a postmortem digoxin level on a patient?

"A. No, I had not ordered it but I also didn't have a case like Pacsai.

"Q Well, what was there about the Pacsai case that led you to order a postmortem digoxin level?"

And your answer was:

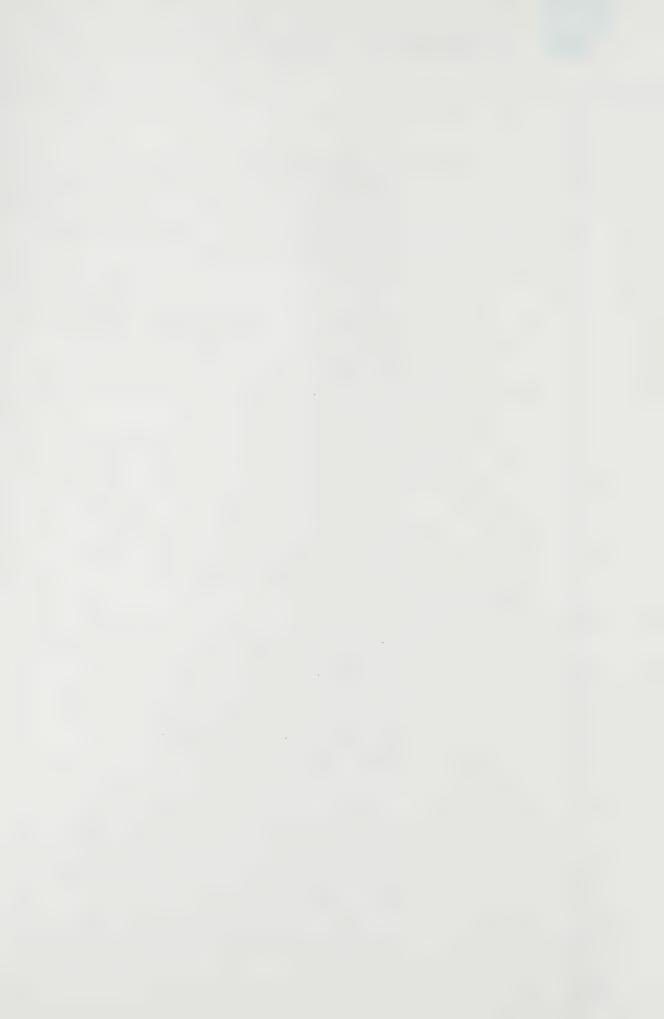
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TORONTO, ONTARIO

"Well, the clinical history of these various conduction disturbances, arrhythmias, problems with potassium are really minor or almost no anatomical findings.

"Q. Was there anything else in the clinical history of the child, Doctor, that influenced you to order a post-mortem digoxin level?

"A. No, not really, nothing. That's based solely on clinical information."





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I take it, Doctor, then you were motivated to order a postmortem digoxin level in the case of Kevin Pacsai first upon the basis of your review of the medical chart and your recognition that Dr. Costigan had twice reported a query about digoxin toxicity?

A. Yes.

Q. These two notes were one factor; is that correct?

A. Well, maybe this discrepancy or which appears to be a discrepancy would be due to a lapse of memory.

Q. Well, Doctor, my only point at this stage is this: the things that you took into account --

A. Yes.

Q. -- were several.

A. Yes.

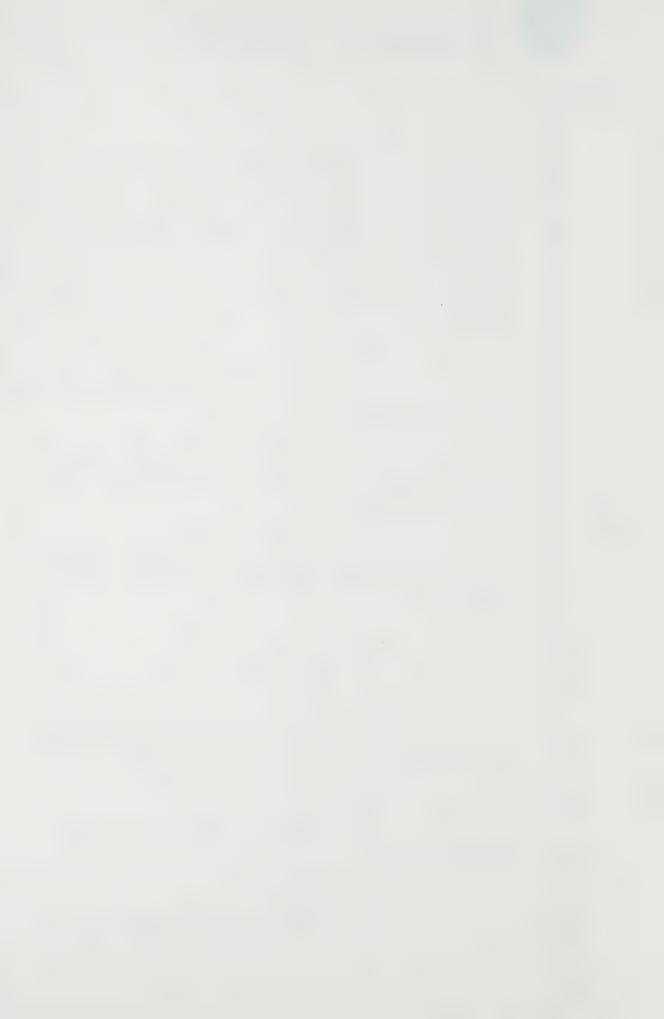
Q. First the two notes written by Dr. Costigan. Do I have that correctly?

A. Yes.

Q. And he had directly queried digoxin toxicity.

A. Yes.

Q. And you read that not once but



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twice in the chart?

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A. Yes.

Secondly you noticed on your review of the chart because you personally reviewed in this case the arrhythmias that had been experienced by the child?

> A. That is correct, yes.

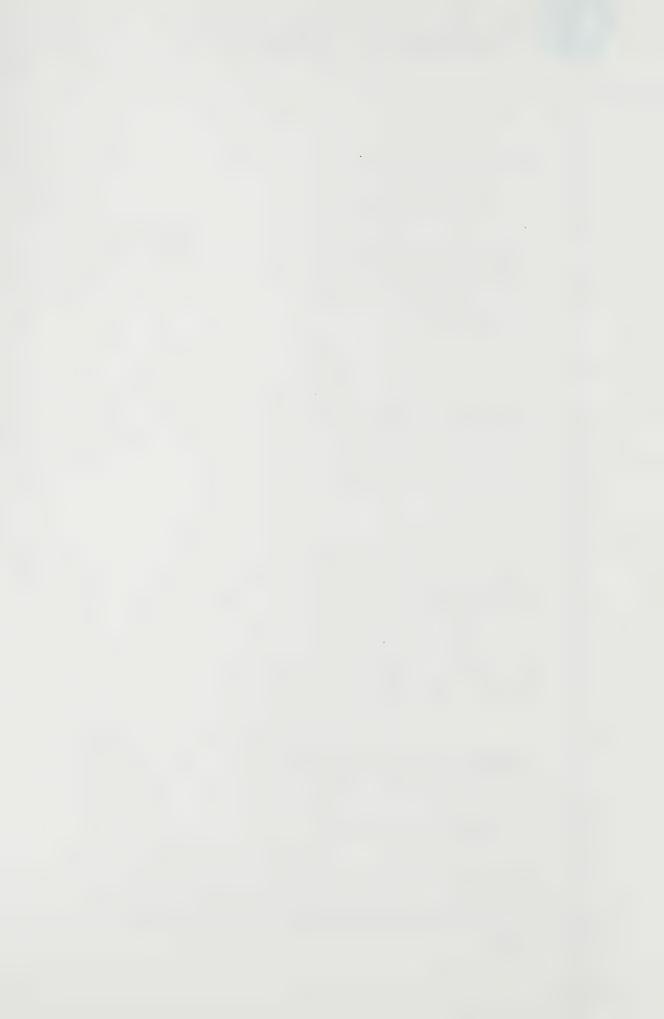
0. And you noticed as well the recording of conduction disturbances that had been noted during life and you noticed that on the basis of your review of the record?

Yes.

And as well, Doctor, I take it because you suggested you never before had a case like Pacsai that your conversation with Dr. Fowler when he suggested to you that it was a puzzling case, that in itself set this case slightly apart from others that you had dealt with in the past?

A. Yes. This would be before I actually had an opportunity to see the chart when I was talking to Dr. Fowler, so I didn't really know the details of the case.

Q. Well, it was on the basis of all of those factors and your discussion with Dr. Fowler that you proceeded to order a postmortem digoxin level?





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A. Well, not really. I think to be
fair, you know, I considered these various possibilities
and as far as digoxin toxicity is concerned I was not
expecting to get a sky-high level. What I was
expecting perhaps would be maybe slightly higher level
within the therapeutic range.

I understand your evidence, 0. Doctor, as to what you were expecting. What I am asking you to direct your mind to --

> A. Yes.

0. -- is what factor or factors motivated you in the first instance to order the level, and I had thought your evidence to be that it was a number of things that you noted in the medical chart.

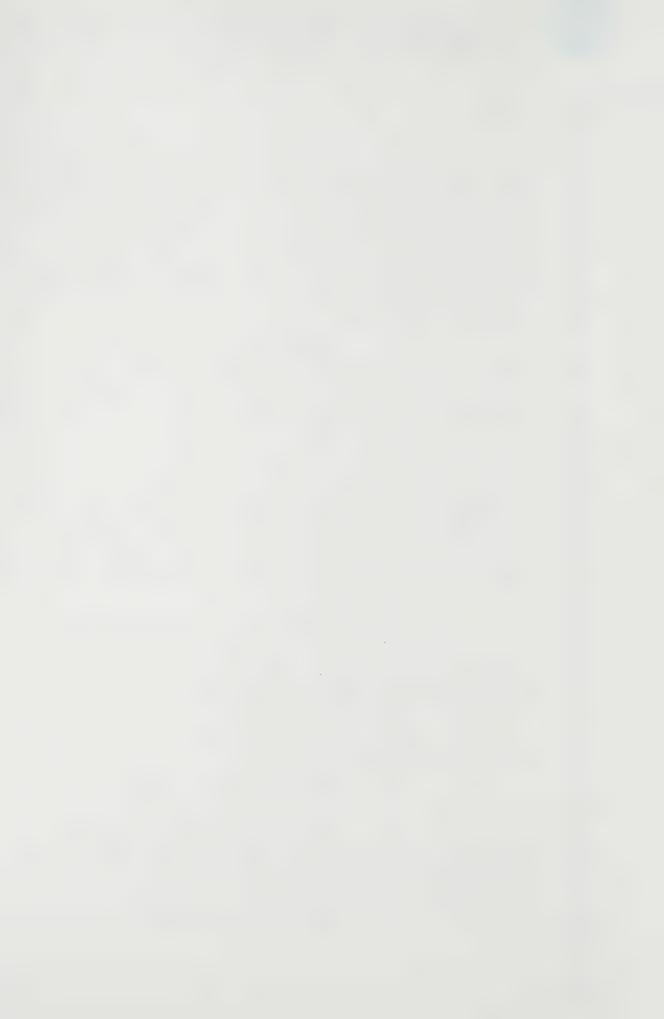
> A. Yes.

That being the arrhythmias, the conduction disturbances, the queries by Dr. Costigan regarding digoxin toxicity, and as well that you had never had a case like Kevin Pacsai before? That is what you told me previously.

That is correct, yes.

And is it your evidence today that those were the factors that you took into account in ordering this digoxin level?

> A. That is correct, yes.





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		Q.	Ι	o you	recal	ll, as	well,	Doc	tor,
one	final	point	in the	cour	se of	your o	discus	sion	with
Mr.	Scott,	telli	ing Mr.	Scot	t that	ther	e was	a we	11
knov	vn and	import	ant in	teract	tion b	petween	n digo	xin	and
pota	assium?	>							

A. Yes.

Do you recall that?

A. Yes.

MS. CRONK: Mr. Commissioner, this evidence appears at Volume 44, page 9045.

That interaction as I understood you to explain it, Dr. Cutz, in your view is that if you have a low potassium level then there is a heightened adverse effect of digoxin on the heart?

> Yes. A.

Do I have that correctly? 0.

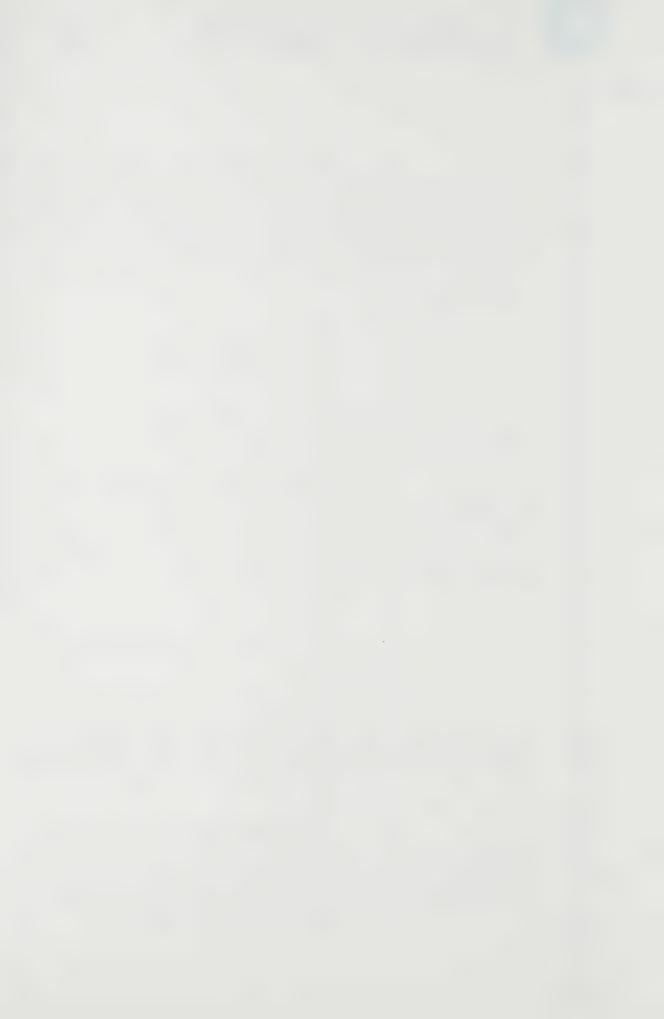
A. Yes.

And I know, Doctor, from your prior evidence that you are familiar with the antemortem and postmortem potassium levels for Kevin Pacsai?

> A. Yes.

Indeed with respect to the antemortem levels your attention was specifically drawn to those by Dr. Tepperman in the coroner's warrant?

> A. That is correct, yes.





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Q.	And you know then, Doctor, on the
child's arrival	at The Hospital for Sick Children he
had a potassium	level of 3.9. Do you recall that?

A. Yes, I believe so, yes.

0. And you recall as well that during the morning on March 12th, the day that he died, he had a potassium level of 9, and then later in the day when another sample was taken at 7:20 he had a potassium level of 7.7. Do you recall that?

I understood the level 9 was only hemolyzed sample which would be inadequate or would not be a reliable sample so for that reason it was repeated.

> 0. Was the 7.7 level --

A. Yes.

-- an unhemolyzed sample?

A. No, that was a proper sample.

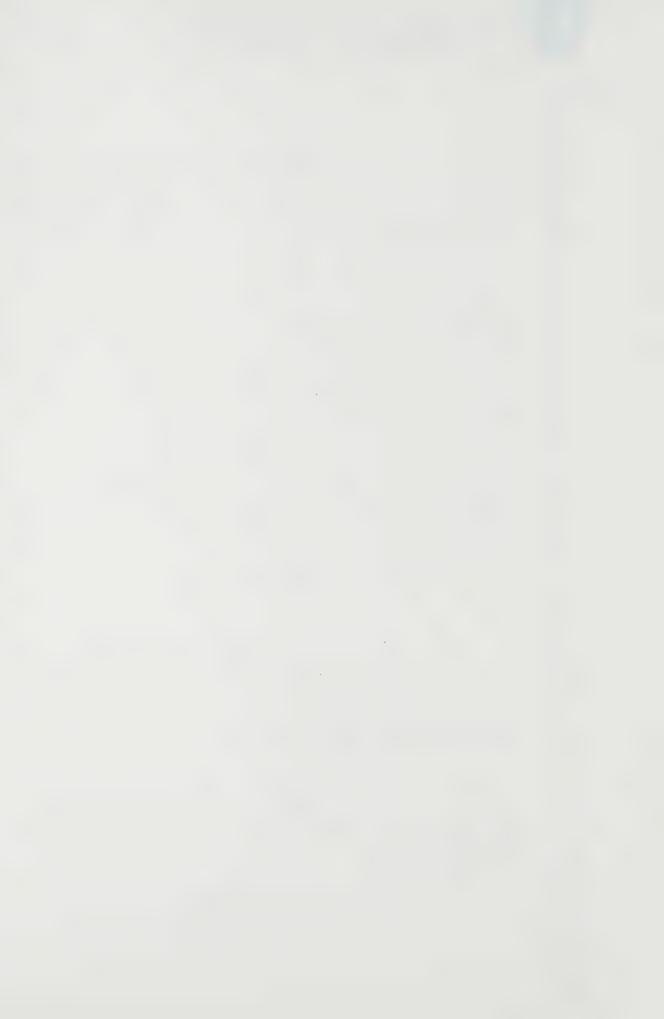
0. All right. But those three samples were recorded during life?

> A. Yes.

Originally the 3.9 on transfer and then a 9 on the day that he died and a 7.7 also on the day he died?

> A. That is correct.

Q. And you would have no queries





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that it was not a hemolyzed sample? That is not a concern with respect to that sample? A.

Well, it is a high level but --

But it wasn't a hemolyzed sample? 0.

A. That is right, no.

with respect to the final level of 7.7 on the basis

Q. And the postmortem level you previously told us was 11.6?

> A. Correct.

I take it we can agree, Doctor, that Kevin Pacsai's potassium levels during life on the basis of those numbers were elevated by the time that he died well over normal? 9 and 7.7.

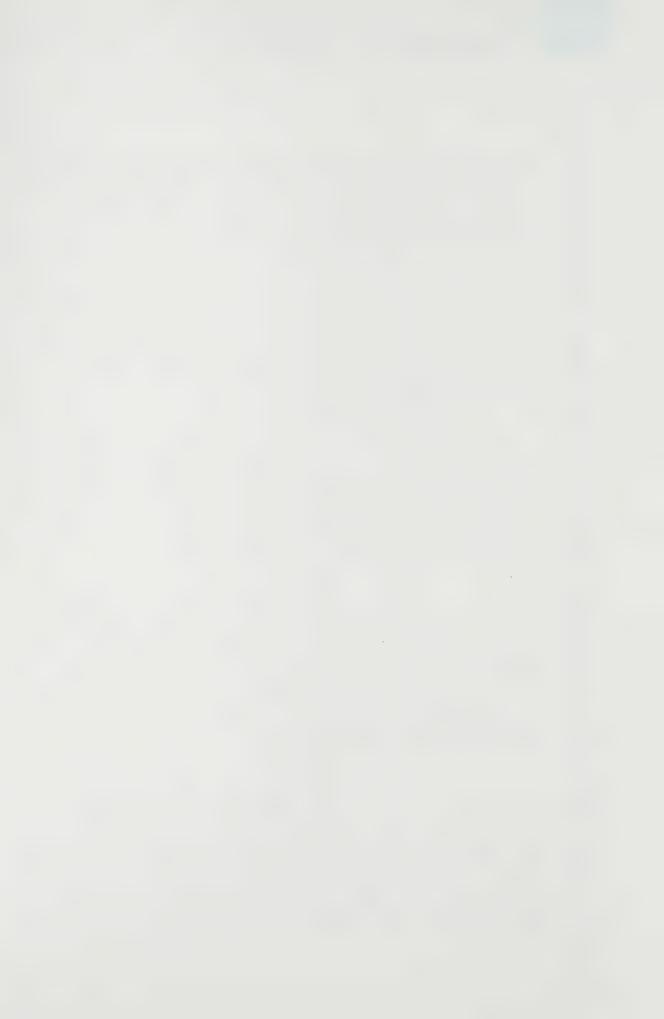
> A. Yes.

All right. So that the interaction between potassium and digoxin which you described to Mr. Scott would not I take it in your view account for a digoxin level of greater than 10 during life and 26 after death?

> A. No.

All right, thank you, Doctor.

And, Doctor, you will recall that Mr. Scott drew to your attention a number of causes of death that were described as such by Dr. Rowe during the course of his evidence and your opinion was sought





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with respect to each as to whether or not you as a pathologist would expect to see any pathological indicators (my word) or findings suggestive of that cause of death if you performed the autopsy.

Do you remember that exchange yesterday?

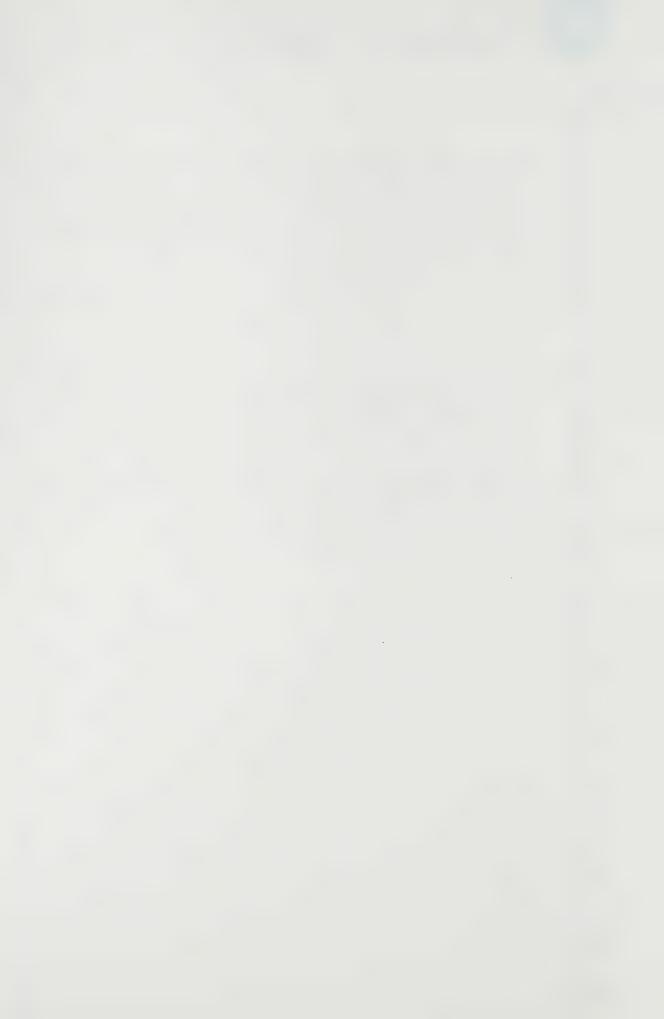
A. Yes, I do.

And your attention first, and I don't intend to go through all of them, Doctor, but I will suggest a number of them to you - your attention first was drawn by Mr. Scott to pump failure, what Dr. Rowe had described as heart failure being a cause of death. Do you recall that?

A. Yes.

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Q. And your evidence in that
regard as I understood it, Doctor, this appears in
yesterday's transcript at page 378. Mr. Scott
asked you, Doctor, whether there were cases where
you would not expect to see evidence of pump
failure at autopsy and your answer was:

- A. Yes, in instantaneous type of death you would not see evidence of pump failure.
- Q. So if you had a sudden death which was attributed to a pump failure where there was an anatomical defect, do I understand that you might not therefore see at autopsy any evidence pointing to that cause?
- A. That is correct.
- $\Omega$ . But nonetheless, you could not exclude the cause?
- A. No, yes."

Do you recall that evidence, Doctor?

- A. Yes, I do.
- answer at the end to mean that yes, you could not exclude the cause of death, although there was no evidence of it, you could not exclude the cause of death?



D2

Α.	That	is	right.
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O. Doctor, if a child was known to have congestive heart failure during life; if the clinicians had observed factors during life indicative of that condition, I take it that you would see signs or indicators at autopsy of that condition?

A. That is correct, yes.

And you would also expect the pathologist performing the autopsy to see some indication of that condition reflected in the clinical history of the child that is provided to you at the time that you undertake the autopsy?

A. That is correct, yes.

Q. Doctor, is it not also possible that heart failure, what Mr. Scott described as pump failure, could be caused by something other than the anatomical defect which he suggested to you yesterday? What I mean by that is that the pumping action of the heart can simply stop if an administration of a massive dose of a poison such as digoxin was administered, that too would cause the heart simply to stop; would you agree with that?

A. No, it is not that simple.



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As far as what the pathologist sees at autopsy is an indication of what would be called a chronic heart failure. In other words, you have to have some, to allow some time for these changes to develop. Here we are talking about chronic heart failure of days, weeks, months.

O. Yes.

A. And this would not be an uncommon finding in cases with congenital heart disease.

Q. Yes, I understand.

A. Where there is sort of a gradual pump failure.

 $\Omega$ . I understand that there is a distinction, Doctor.

A. Yes.

 $\Omega$ . I understand there is a distinction in a situation where a patient has had chronic heart failure or what I chose to call congestive heart failure.

A. That's right.

Q. And in that situation you have told me that if an autopsy was performed you would expect to see signs of that?

A. Yes, you would see signs of



D4

that, yes.

Q. Then the other situation, the distinction I understood to be drawn yesterday was the situation where there is instantaneous death and pump failure. I understood you to say in that situation you would not expect and normally would not see pathological findings suggestive of pump failure, that is the other situation; is that correct?

A. Yes, this would refer to say a normal person with sudden pump failure.

Q. Yes.

A. Then you wouldn't see these changes in the organs. But if you are talking about a patient with chronic congestive heart failure who died suddenly for other reasons than his heart disease, then you would still see the changes of heart failure.

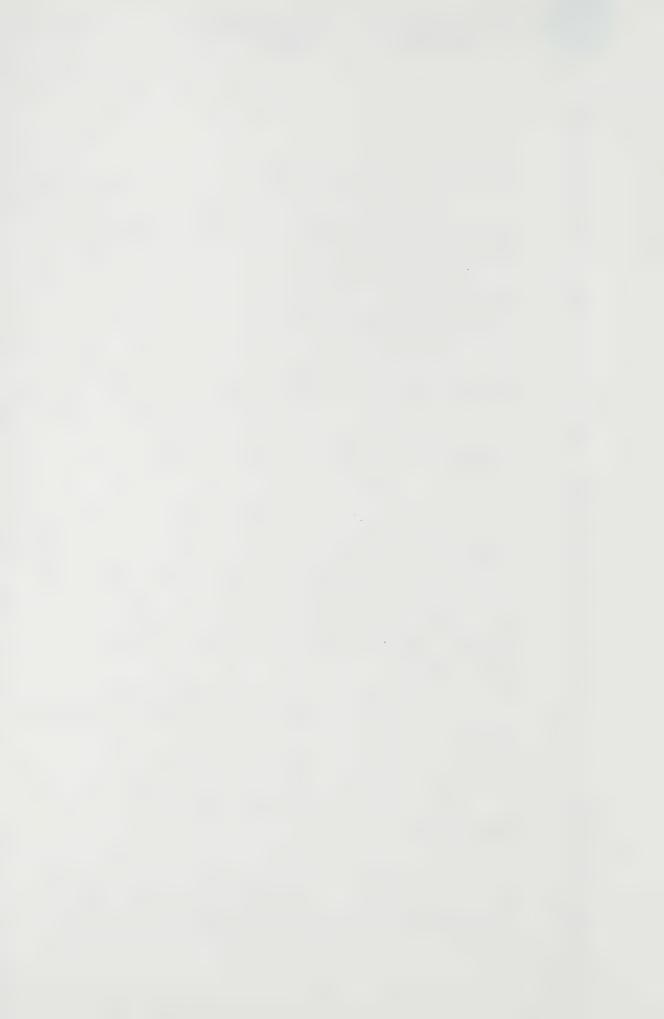
 $\Omega_{\bullet}$  All right. That is my point, Doctor.

A. Yes.

Q. If there are two distinct situations.

A. Yes.

 $\Omega_{\star}$  And the first is one where the patient has been recognized during life to suffer



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right.

from heart failure, or congestive heart failure.

A. Yes.

Q. Then you will see signs of that at autopsy?

A. That is correct, yes.

 $\Omega$ . That is situation number one,

A. Yes.

O. Situation number two is where the patient dies instantaneously, and in that situation you have told us you might not see pathological findings indicating pump failure at autopsy, is that correct?

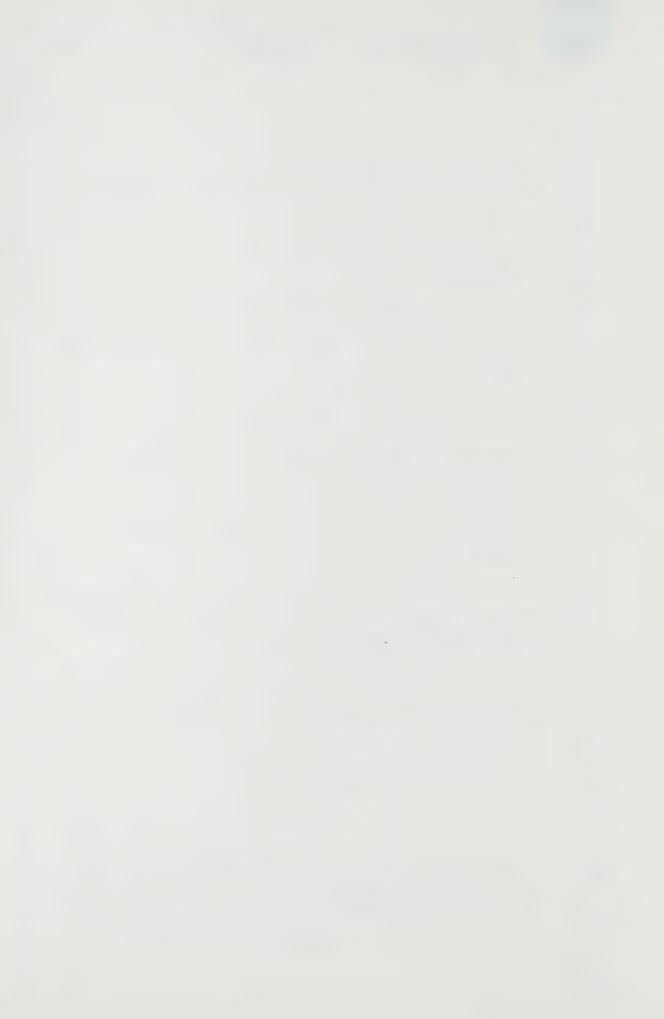
A. Well, this would refer to a patient who has a condition not predisposing to heart failure and/or healthy individual.

Q. My only suggestion to you,
Doctor, was if at autopsy you were confronted with
that situation, a patient that was not known to have
an anatomical defect in the heart.

A. Yes.

Q. You would, in that situation, if the patient had died instantaneously not expect to see any pathological indications of pump failure.

A. That is correct.



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Ω. My suggestion to you is that in that situation it is also possible that the heart pumping activity could be caused to stop, thus causing the death of the patient?

A. Yes.

Q. If a lethal dose of a poison was administered, that too would have the result of causing the pump to stop.

A. Yes, I believe so.

Q. And that could be the case with digoxin?

A. Yes, I believe so, yes.

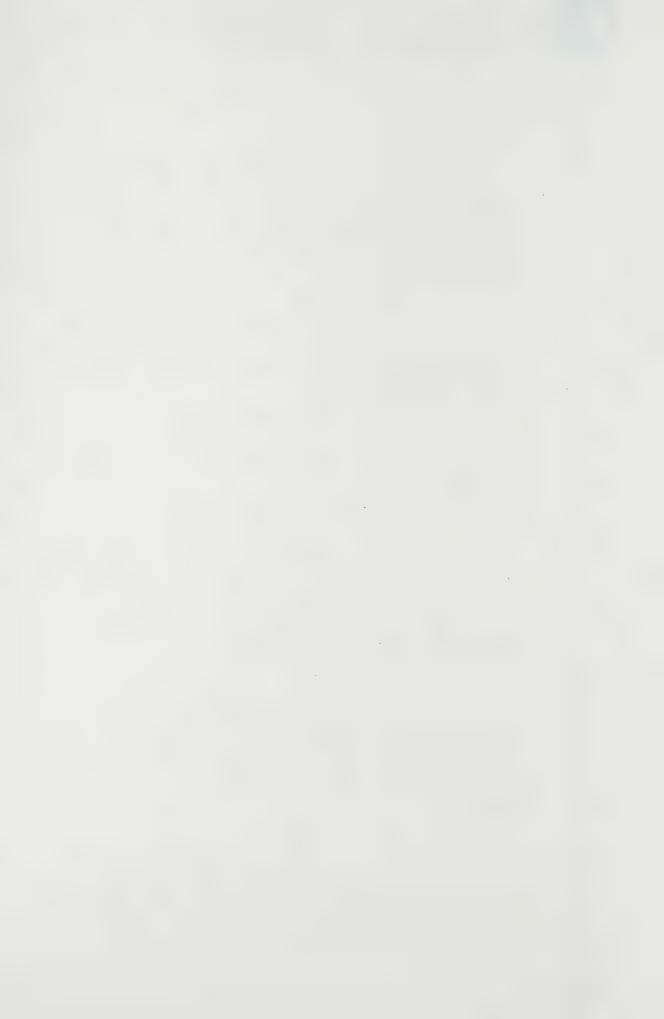
Ω. Thank you, Doctor. The second potential cause of death to which your attention was drawn by Mr. Scott yesterday was instability of temperature; do you recall that?

A. Yes.

Q. You told Mr. Scott, as I understood your evidence, that there would no pathological indictors of that kind of a cause of death?

A. Yes.

 $\Omega$ . Doctor, I would take it that we can agree that if the instability of temperature in any particular patient is of and in itself



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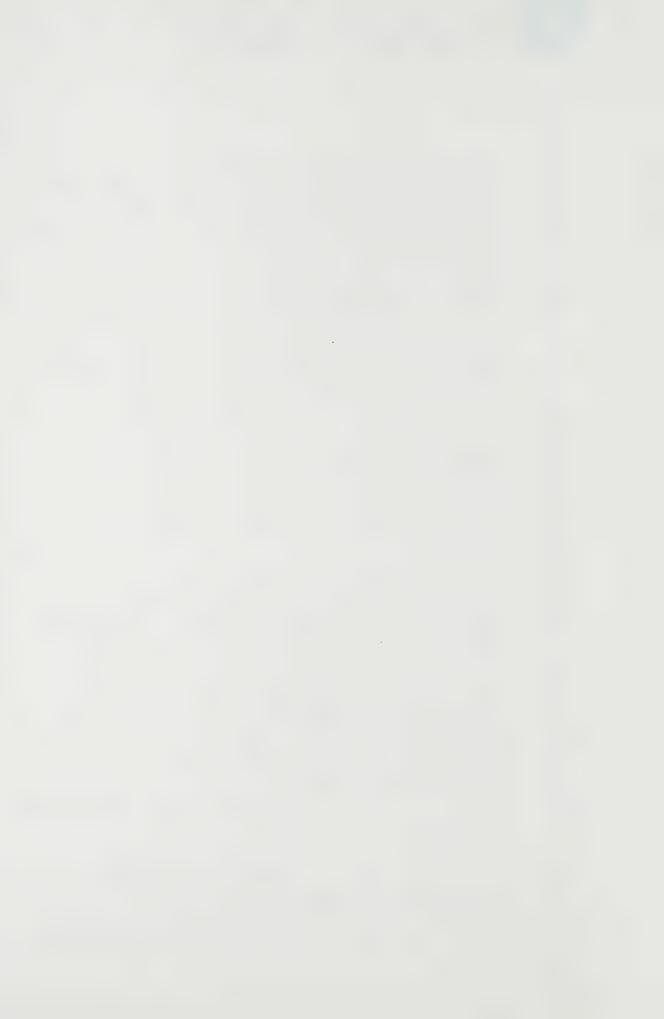
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triggered by an underlying condition, then you may very well see pathological findings which are suggestive of that condition. For example, if the patient has an overwhelming infection, that might result in instable temperature readings, correct?

- Well during infection you Α. would tend to have high temperature, but that would not be interpreted as unstable temperature.
- 0. Are there not conditions during life, Doctor, caused by disease, or a condition that could be suffered by the patient, which could result in instable temperatures, or do you know?
- Α. This would be common in premature small birth weight infants. Due to the small body weight, low reserve and immaturity of the central nervous system that you get this instability, and they tend to get hypothermic, that is they have lower temperatures than what you normally would have.
- O. Are there signs of hypothermia at autopsy?
- Α. No, you cannot detect it, this is something you observe during life.
  - Now if we make the assumption Ω.



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that the patient involved is not a premature baby.

A. Yes.

Q. That is suffering from that hypothermia, but it is another infant, is it not a fact that there are conditions where diseases which could be experienced or suffered by that child during life which would cause fluctuations in the child's temperature, it could go up, it could go down.

A. It would be uncommon in older or full term infants or adults, it would be fairly uncommon.

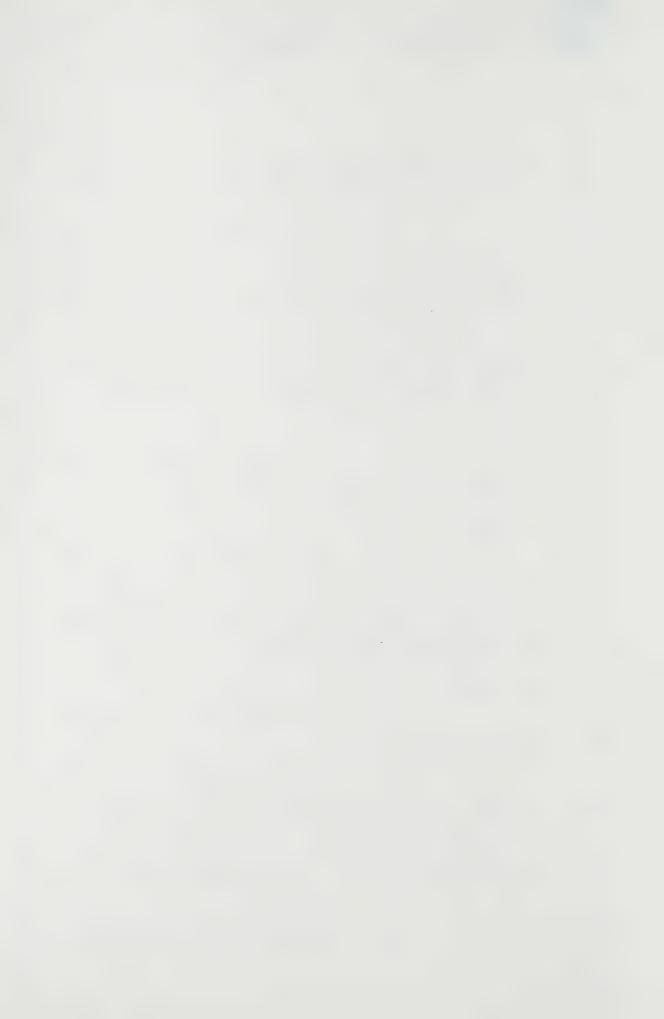
Ω. And if happened, Doctor, and if it was caused by an infection, or a disease of some kind, I take it it is possible that you would see evidence of that infection or that disease at autopsy?

A. Yes, it would be a secondary type of phenomena, yes.

Q. Thank you, Doctor. Then thirdly, your attention was drawn by Mr. Scott to four kinds of conduction failures that had been described by Dr. Rowe. Do you recall that?

A. Yes, I do.

 $\Omega$ . And you told Mr. Scott, as I



understood it, that at autopsy in your view there would no pathological indicators of those kinds of conduction failures unless a conduction study had been undertaken; do I have that correctly?

- A. That is correct.
- Q. Are you saying, Doctor, in that regard, that in every case, in order to rule out a malfunction or a defect in the conduction system of the patient at autopsy, a conduction system study must be undertaken?
- A. Well, I think it depends on the facilities at the time and money available to do such a study. As was mentioned before it requires a considerable ---
- Q. Time, expenditure and financial concern as well?
  - A. That is right.
- Q. Leaving aside, Doctor, the difficulties in undertaking this study.
  - A. Yes.
- Ω. My question to you was, was the import of your answer yesterday intended to mean or to convey that at autopsy as a pathologist, you would be unable in any case to rule out a conduction system defect, or a conduction system abnormality



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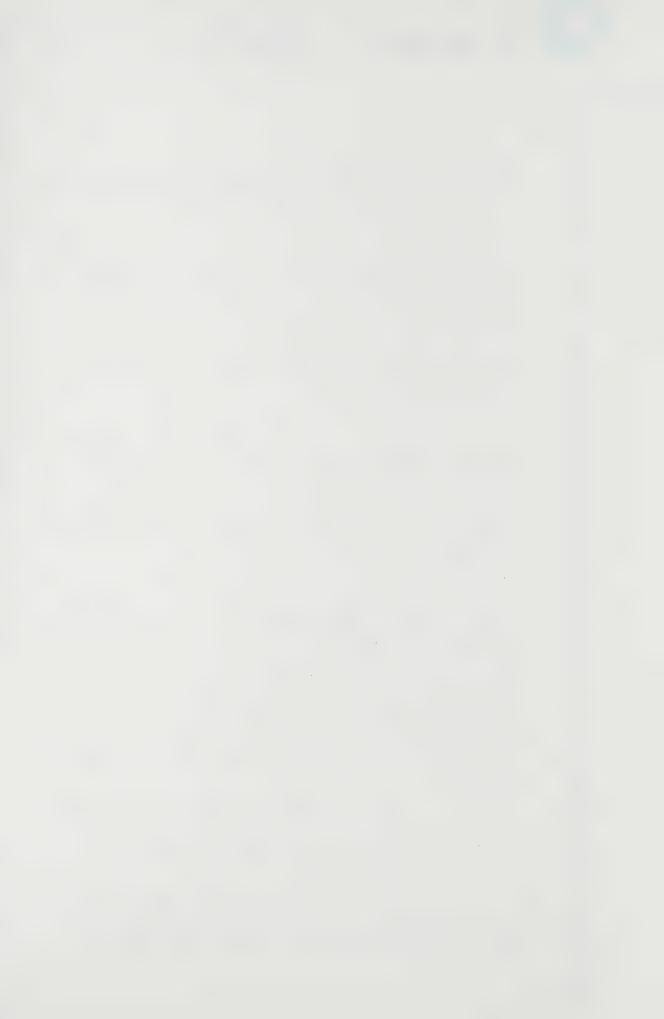
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without a conduction system study being undertaken?

- A. That is correct.
- Q. Does that mean, Doctor, that at every autopsy that you performed, you cannot with certainty say that the cause of death might not have been a conduction disturbance, because we know that those conduction studies have not been done in the Hospital?
- A. Well, there has to be some degree of suspicion that this actually happens. There would be clinical and electrophysiological indicators which would tell you this patient had this disturbance.
- Q. Is it not possible, Doctor, as well, that at autopsy as part of the pathological findings you might see evidence of an electrolyte imbalance, or a conduction disturbance, that that is something you might see as part of the test, the detailed test that are conducted in a normal autopsy?
  - A. No, you would not see that.
  - $\Omega$ . You would not see that?
  - A. No.
- $\Omega$ . No electrolyte tests are done as part of the normal autopsy procedures?



	Α.	Well,	it's	being	done	on	ć
selective	basis.						

Q. And if they were done,

Doctor, and if irregularities were shown as a

result of those tests, would that not suggest to

you as a pathologist that there might be some

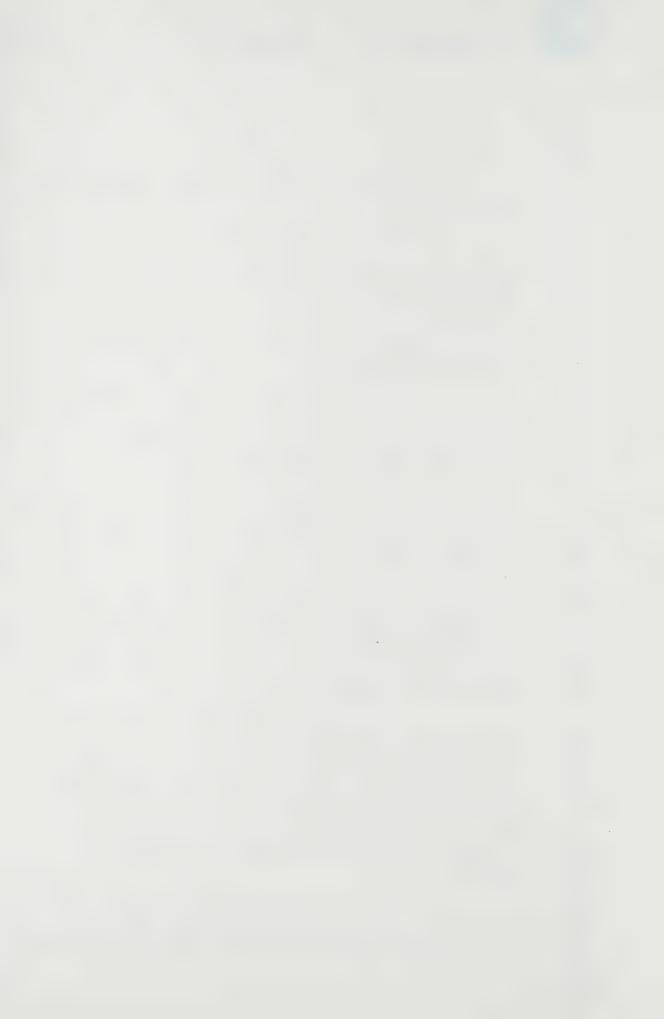
conduction disturbance?

A. I don't see the connection between the electrolytes and the conduction, I don't think there is any connection.

Q. Doctor, then if the electrolyte readings will not provide you with that kind of a basis, is there any other way at autopsy in which you as a pathologist could determine whether or not a conduction disturbance had been sustained by the patient involved without relying purely on what had been observed during life?

A. I think the purpose of the pathology examination would be to correlate the observation in life which would be the electrophysiological abnormalities with actual anatomic findings, structural findings in the conduction system.

Q. Then I take it, Doctor, that you can rule out a conduction failure, or a conduction

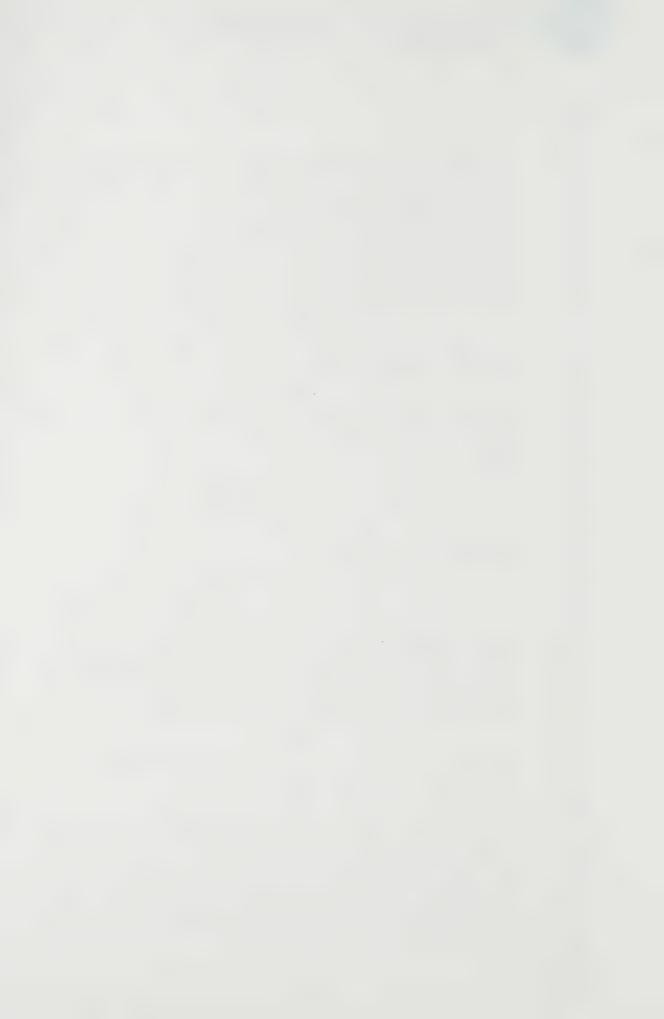


disturbance as a possible cause of death without doing a conduction system study, if there has never been any suggestion or any suspicion in the clinical history of the patient of a difficulty of that kind. Is that something you would be prepared to rule out?

A. Well, I think you would not consider it unless there is good clinical evidence.

Q. Thank you, Doctor. And you wouldn't need a conduction system study to tell you that?

- A. That is right.
- Q. All you would have to do is look at the child?
  - A. That is right.
- $\Omega$ . Doctor, finally, the fourth cause of death that I will simply draw to your attention that was discussed yesterday between Mr. Scott and yourself as you may recall was apnea.
  - A. Yes.
  - Q. Do you remember that?
  - A. Yes.
- Ω. As I understood your evidence with Mr. Scott yesterday, you told him that you wouldn't normally expect to see anything at autopsy suggestive of apnea unless a detailed examination of the brain



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had shown changes in the brain; do I have that correctly?

- A. That's correct.
- Q. Doctor, am I correct that a microscopic examination of the brain is part of a normal complete autopsy conducted at the Hospital for Sick Children?
  - A. That is correct, yes.
- Q. So that in the circumstances of a normal autopsy that detailed microscopic examination of the brain would be undertaken?
  - A. That is correct.
- Q. And once undertaken, if there were any symptoms indicative of apnea, as for example gliosis for scarring of the brain stem, that would present itself during the course of those microscopic examinations?
  - A. Yes.
- Q. And in that sense, Doctor,
  can we agree that by the time you complete a
  normal routine autopsy on any patient at the
  Hospital, if that patient has suffered apnea during
  life you would well expect to see some indication of
  that in the brain based on the microscopic examination?
  - A. Well, I think it is not as

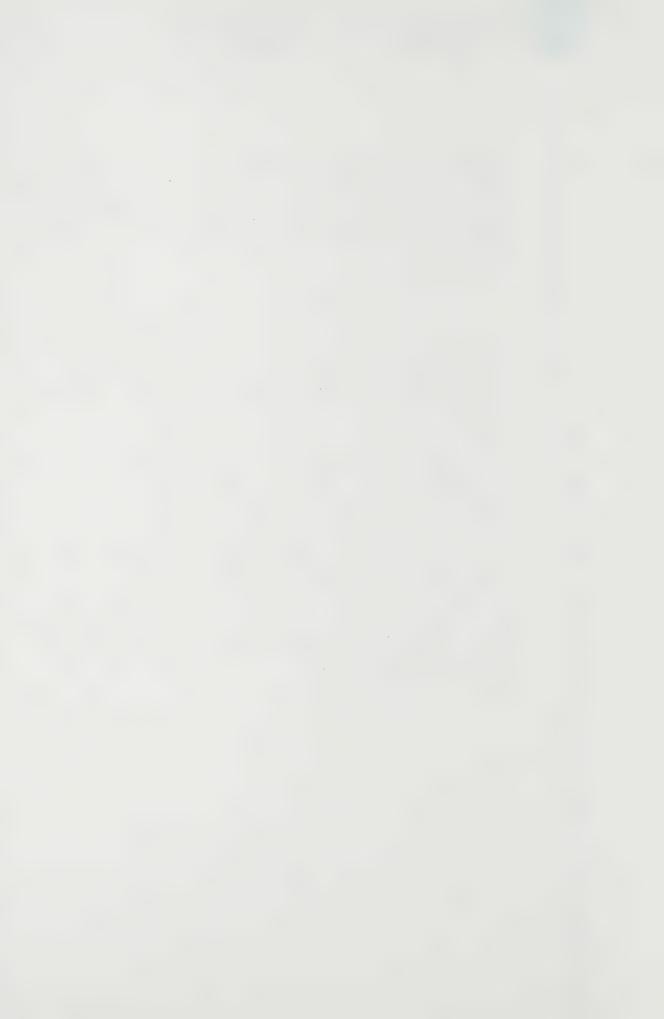




simple as it is put. But you know a neuropathologist and a pathologist trying to make an association, and apnea means stoppage of breathing, this is something you observe.

 $\Omega$ . Yes.

A. And in doing autopsies on patients who died, you know, with these kinds of symptoms, usually you see repeated apneas, and this happens again with premature babies who tend to suffer from this, low birth weight babies. Then you try to correlate, you know, you know these were the symptoms and the pathological examination you look at the changes which might explain these clinical symptoms of apnea, and the association which has been made is that the changes in the brain stem which we know are the centres of respiration, but this is hypothetical.



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You can verify it to an extent in an experimental animal but to be saying that if there is a patient who suffered with apnea and he doesn't have the lesions in that particular area, it doesn't rule it out.

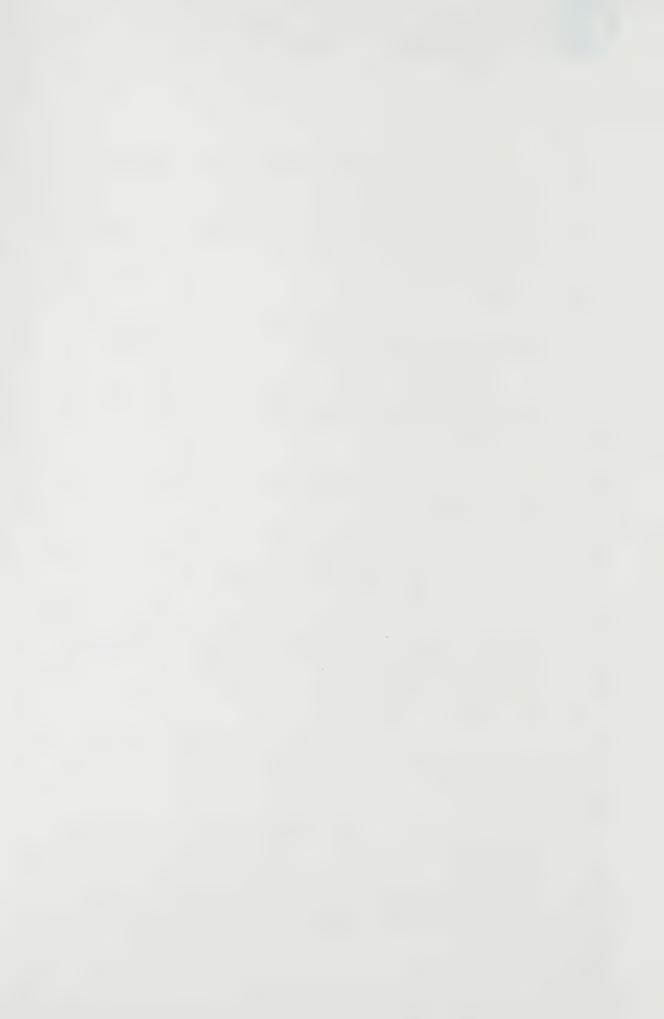
Q. No, I accept that, Doctor, perhaps I put the question badly. Can we agree, can we go this far together, that apneic spells are commonly associated with hypoxia. Would you agree with that?

A. Well, that would be part of the whole syndrome.

Q. All right. And would you agree with me that at autopsy if a patient had, if the cause of death was apnea, if an apneic spell had been suffered and the patient was suffering from hypoxia there are indicators which would be evident at autopsy of a hypoxic condition?

A. Yes, if it is chronic enough, if there is a long enough duration then you might see it, yes.

Q. All right. And similarly, and perhaps the fairest way to suggest this to you, Doctor, is that Dr. Becker has testified extensively with respect to what he regards as being the pathological





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indicators of Sudden Infant Death Syndrome and missed-SIDS and he has indicated in that regard that one of the factors which indicates apnea and hypoxia is gliosis or scarring of the brain and that he would expect in that circumstance to see that at autopsy. My suggestion to you only is that if apnea has been suffered you might very well see as a result of the detailed examination of the brain evidence of gliosis or scarring of the brain and as well evidence of hypoxia?

A. Yes, that would be in a typical case, and this again is not a thing you will find in a hundred per cent. I think it probably came out thus far that the medical knowledge is not ---

Q. I understand your evidence,

A. --- complete and we are really dealing with hypothesis.

THE COMMISSIONER: Just a moment.

MS. CRONK: Perhaps to anticipate ---

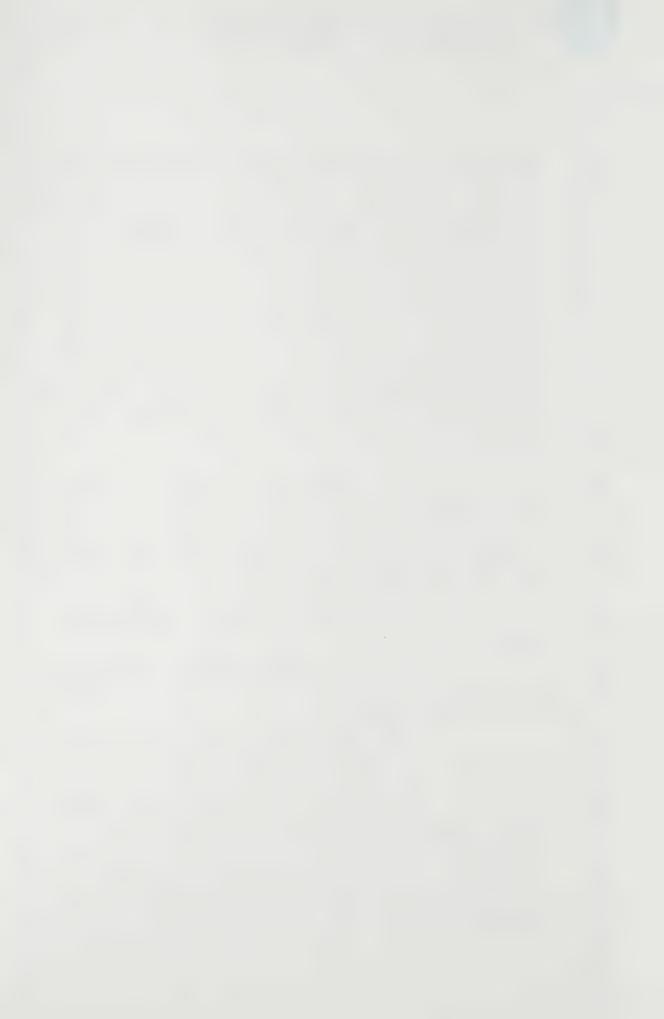
MR. ROLAND: Yes. I am sure my friend

didn't leave this out of her interpretation of

Dr. Becker's evidence on purpose but as I recall

Dr. Becker he also said that the spells had to occur

at least two weeks before the death or the autopsy to





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show up even as indicators where, as my friends have indicated, as an indicator, that is, if the apneic spell occurred within two weeks of the autopsy there likely would be no indicators.

MS. CRONK: That's fairly put, thank you, Mr. Roland.

Doctor, the only point and then I will leave this issue is, in your opinion and your evidence has been that if periods of apnea are experienced during life and the time interval is sufficient between the time that the apneic period is suffered by the patient and the time of death, in those circumstances you would expect to see evidence of that at autopsy?

Yes, you would.

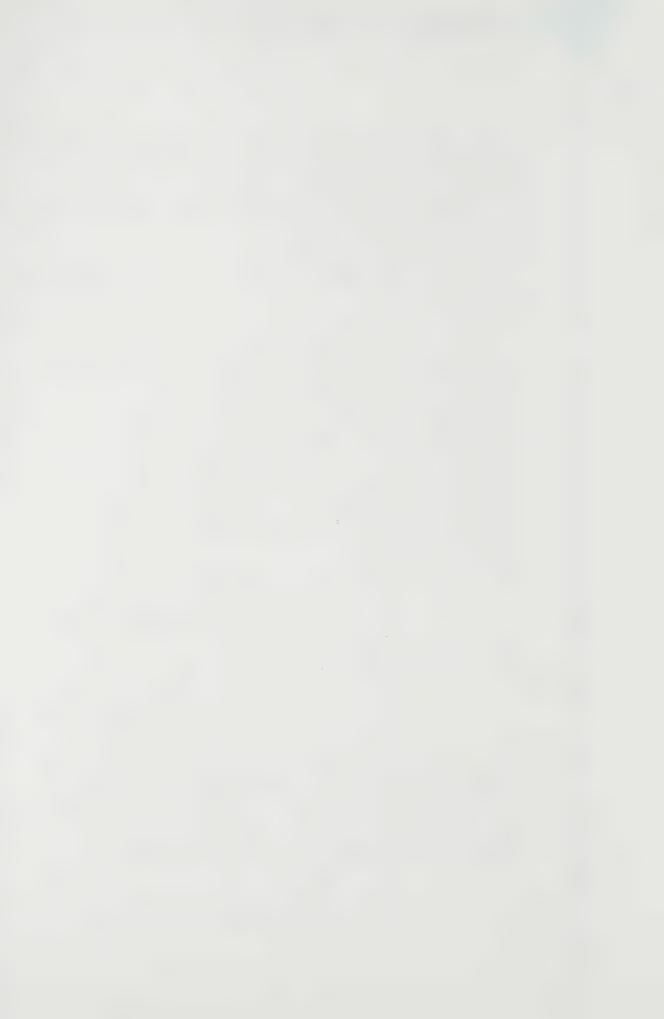
All right. And in that sense you would agree with Dr. Becker?

> A. Yes, I would.

All right. And similarly to be Q. fair, as Mr. Roland points out with respect to evidence of hypoxia, if the patient had suffered hypoxia and given a sufficient time interval you would expect to see evidence of that at pathology?

> A. Yes.

At autopsy, I'm sorry.





A. Yes, you would	
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Q. All right. Doctor, I would ask you to make the assumption that at autopsy you find evidence of both those factors of apnea or apneic spells during life and as well evidence of hypoxia. Do you understand the assumption?

A. Yes.

Q. I am asking you to assume that you find that evidence at autopsy?

A. Yes.

Q. All right.

THE COMMISSIONER: I am sorry, could I just interrupt for a moment?

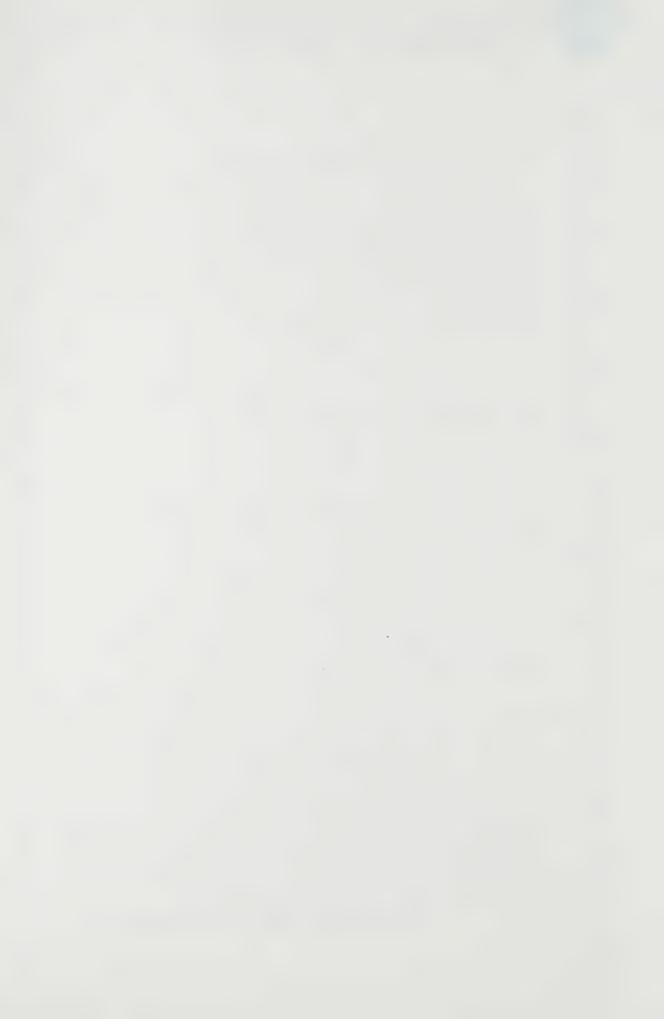
MS. CRONK: I'm sorry.

THE COMMISSIONER: What would the nature of the finding of hypoxia in life, where would you find it, what would be demonstrated?

MR. TOBIAS: Excuse me, Mr. Commissioner, I didn't hear your question to the witness.

THE COMMISSIONER: No. Well, it was you can perhaps incorporate the question in the
answer do you think. Where would you find evidence
of, how would you find or how would the existence of
hypoxia be demonstrated on an autopsy?

THE WITNESS: Well, actually these





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findings are based on a rather large study from the United States by Dr. Naeye, who examined several hundred ---

THE COMMISSIONER: I don't want you to go into a great deal of detail. I want you to say whereabouts in the body.

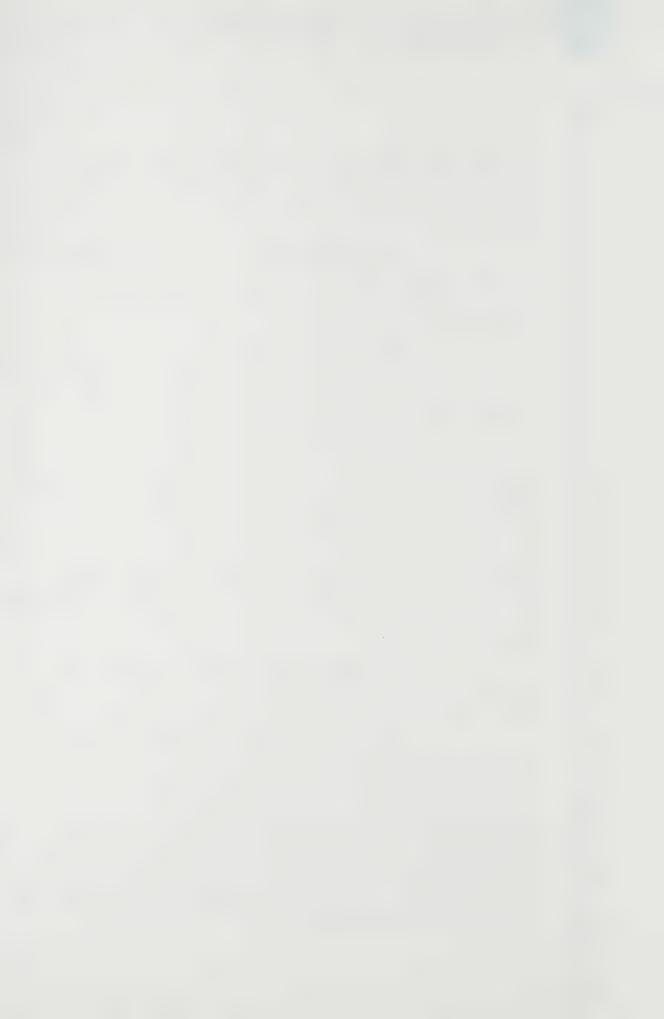
THE WITNESS: Yes.

THE COMMISSIONER: How do you find - when a child lacks oxygen how do you find ---

THE WITNESS: Yes, but what I would like to explain is that this study is based on a large number of patients dying of crib death and by doing detailed morphometric measurement studies in these cases, this study came to the conclusion that these babies have increased fat, they have thickened pulmonary arteries.

THE COMMISSIONER: Those are all the same symptoms that Dr. Becker said?

THE WITNESS: That's correct, yes. is assumed to be on the basis of, or the hypothesis proposed was that these changes are due to chronic hypoxia, alveolar or pulmonary hyperventilation in these patients. So, this is a finding which is based on a study and which is not a hundred per cent accepted by everybody in the field.





THE COMMISSIONER: No, but hypoxia is lack of oxygen and apnea is lack of breath. Are they the same things?

THE WITNESS: Well, apnea would lead to lack of oxygen.

THE COMMISSIONER: You can't I take it
have a lack of oxygen. As long as you have breath
there is lots of oxygen in the air, is that the thought?
THE WITNESS: Well, you can have hypoxia
if you go to a high altitude then the oxygen is ---

THE COMMISSIONER: And you lack the oxygen that comes in the air?

THE WITNESS: That's right.

THE COMMISSIONER: But that is not in The Hospital for Sick Children?

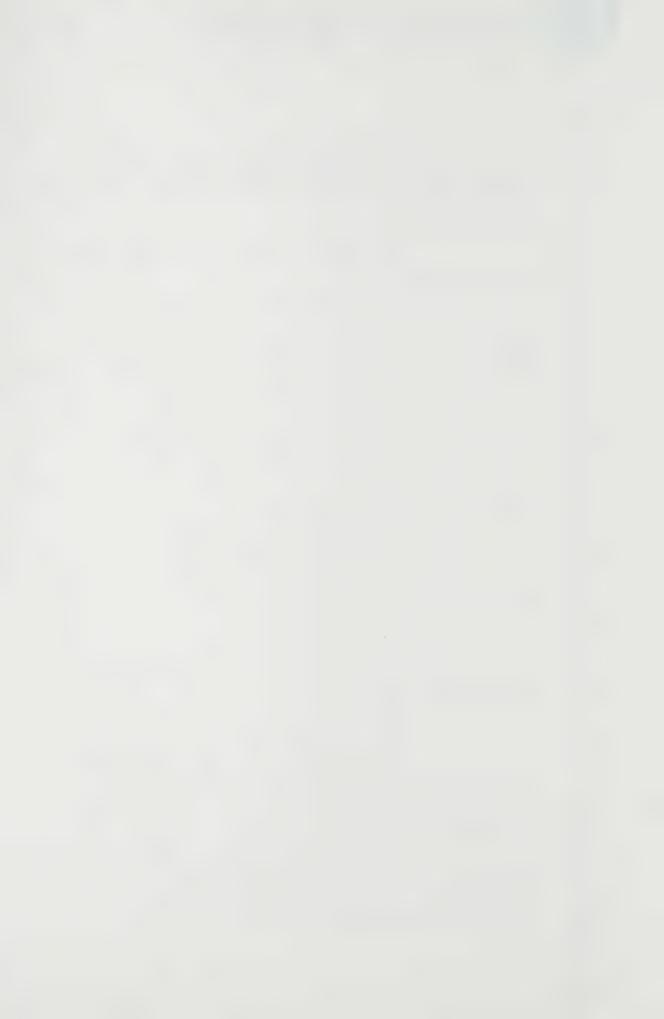
THE WITNESS: No.

THE COMMISSIONER: They keep an adequate supply of air there?

THE WITNESS: That's right.

THE COMMISSIONER: Well, when a doctor refers to hypoxia and refers to spells of apnea. Is he talking about the same thing?

THE WITNESS: No, spells of apnea would be the ones which lead to hypoxia. Like, if these spells are of a long duration --



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THE COMMISSIONER: Yes.

THE WITNESS: -- then that would lead to chronic ---

THE COMMISSIONER: Apnea is the disease and hypoxia is the result of the disease?

THE WITNESS: Is the consequence of it, yes.

THE COMMISSIONER: All right.

MS. CRONK: Doctor, just to explore that briefly so I understand further.

THE COMMISSIONER: I interrupted your question but I would think the answer then becomes fairly obvious.

MS. CRONK: That's fine. One more question on that if I may, Mr. Commissioner.

THE COMMISSIONER: All right.

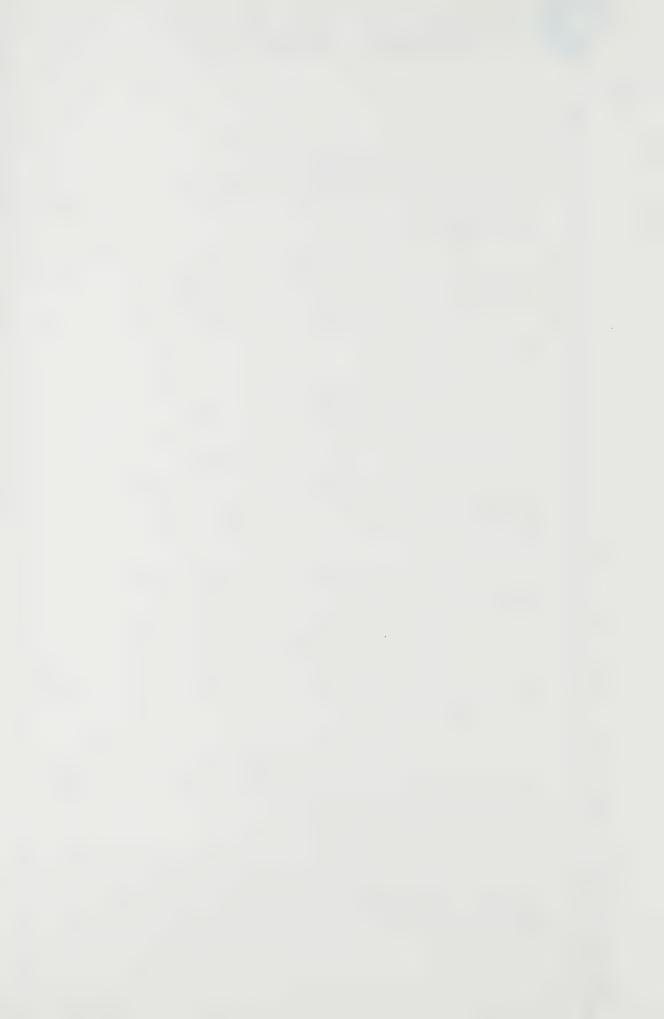
 $\qquad \qquad \text{MS. CRONK:} \quad \text{Q. Doctor, just for purposes} \\ \text{of illustration.}$ 

A. Yes.

Q. In the Kevin Pacsai preliminary autopsy report, for example.

A. Yes.

Q. You include reference to this finding: hemorrhages on the thymus and recent hemorrhage of, and I may be mispronouncing it, falx



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cerebri are most likely related to hypoxia. Do you recall that finding?

A. Yes.

Q. Were those findings not in fact indicators at autopsy of hypoxia in that child?

A. Well, this again is in the context of trying to explain those findings and, as I understood the infant Pacsai, when he was admitted to the Sick Children's Hospital he had suffered a cardiac arrest and was resuscitated. So that he had a period of hypoxia and I was tying these two things ...

Q. Together.

A. Together, yes.

Q. When you observed those hemor-rhages in those locations at autopsy, Doctor --

A. Yes.

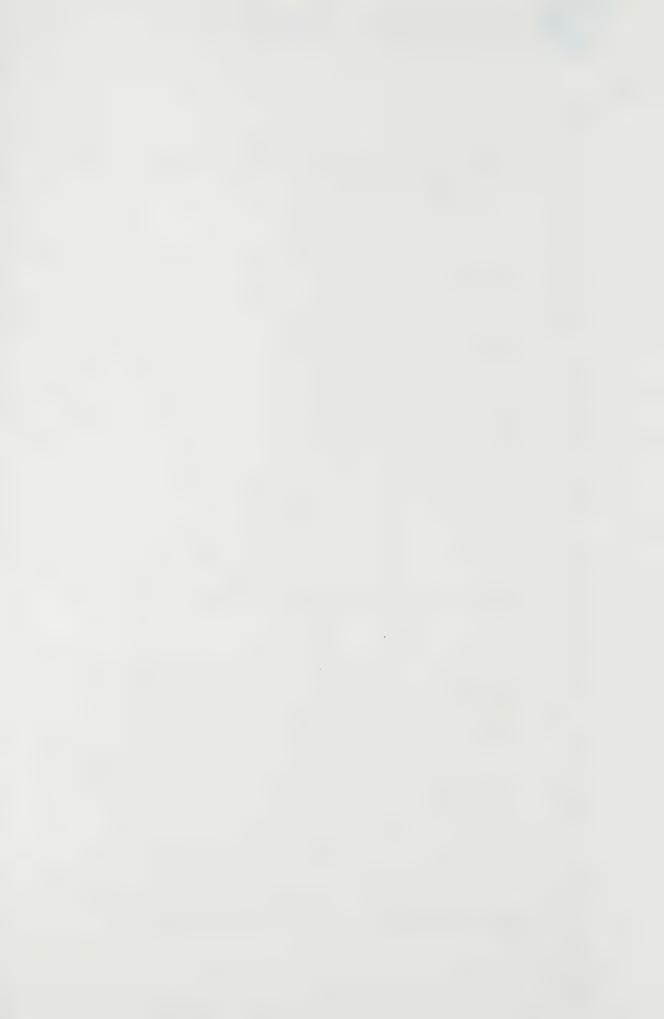
Q. -- did that not suggest to you, was that not regarded by you as being evidence of the hypoxia that you knew had been experienced during life?

A. Well, these would be signs like hemorrhages, these would be signs of acute hypoxia.

Q. Thank you, all right.

A. As opposed to chronic.

Q. That is one kind of pathological indicator in this case of acute hypoxia?





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A. That's right, yes.

Q. All right. And similarly, Doctor, can we agree that gliosis or scarring of the brain stem is a factor that would be commonly regarded by pathologists as being an indicator of apnea?

A. Well, it is thought to be the basis of apnea.

Q. All right. And if you find that you think apnea?

A. Well, you would think that, you know, this patient should have had apneas.

Q. Thank you.

A. Now, you have a case where you find these lesions and yet there is no clinical evidence that he suffered from apnea?

Q. And that I take it doesn't mean that the patient didn't?

A. That's right.

Q. I guess it could be acute apnea?

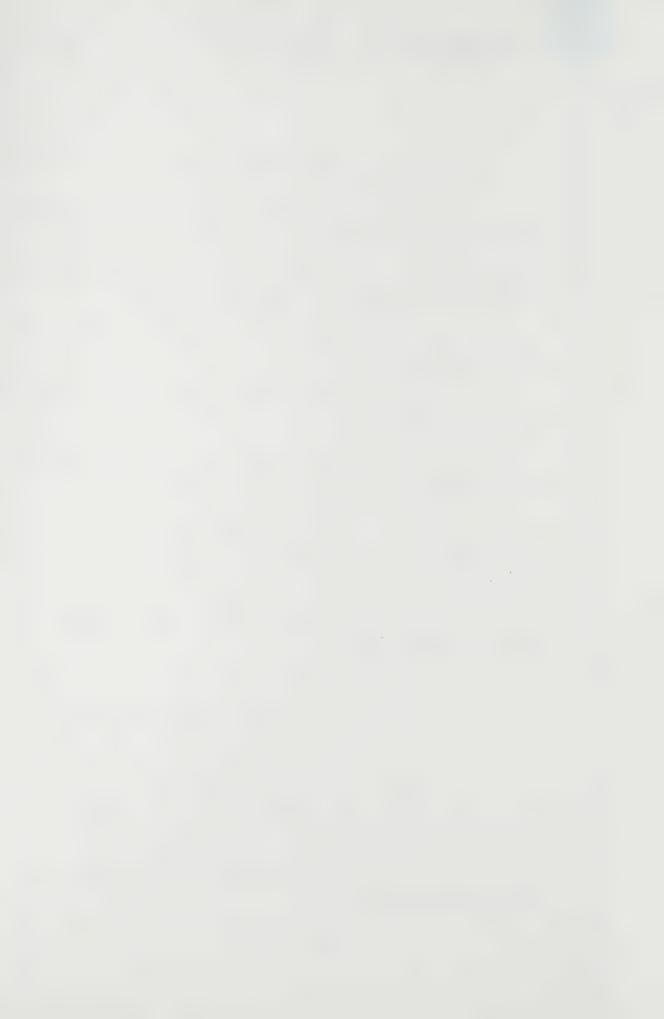
A. It was not observed.

Q. It could be acute apnea?

A. No, these lesions you only get after chronic apnea of several weeks' duration.

Q. So, it may have happened and simply not been detected?

A. That's right.





		Q.	All	righ	t. I	But	when	you	see
that	finding	that's	what	you	thin	k of	E?		

A. That's right, yes.

Q. All right. Doctor, one final area, and this relates to, again, the postmortem sample that was taken for digoxin assay in respect of Kevin Pacsai.

A. Yes.

Q. You will recall during the course of your cross-examination by Ms. Forster yesterday, as I understood the exchange, you suggested that bacterial contamination of that sample might be possible from the surrounding air. Do you recall that?

A. Yes.

Q. And it is because of that

possibility, as I understand it, Doctor, the possibility

that bacteria in the air can contaminate a sample

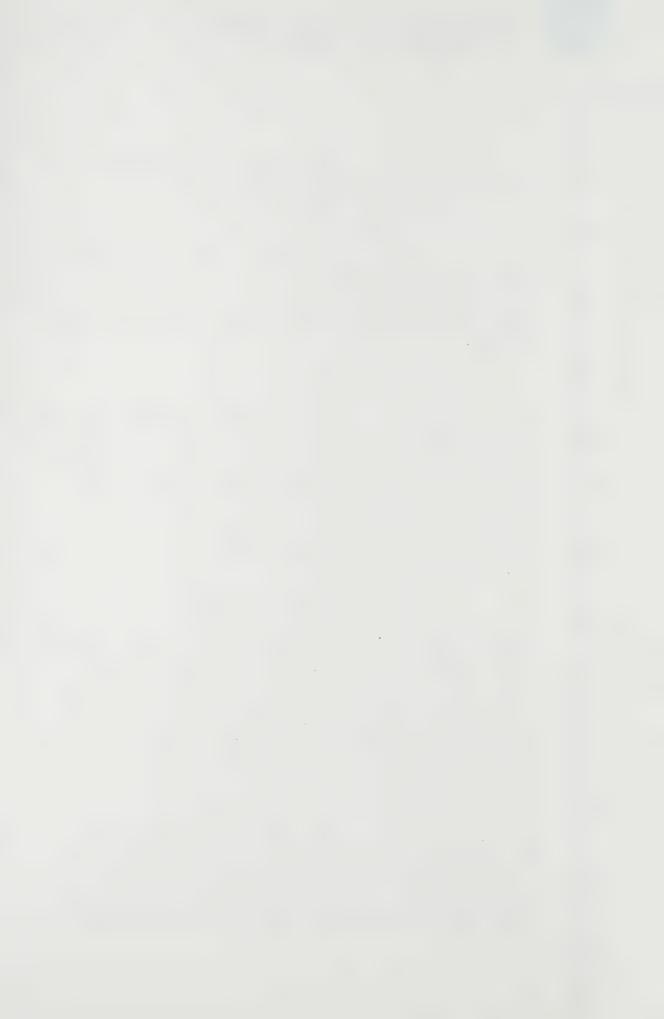
that's been taken that pathologists when they take

samples for cultures sterilize this site by using a

heated instrument, that is exactly why they do it,

is that right?

A. Well, no, the sterilization is for the purposes of sterilizing the area where you puncture, where you make the puncture and enter the vessel and there may be contamination from postmortem





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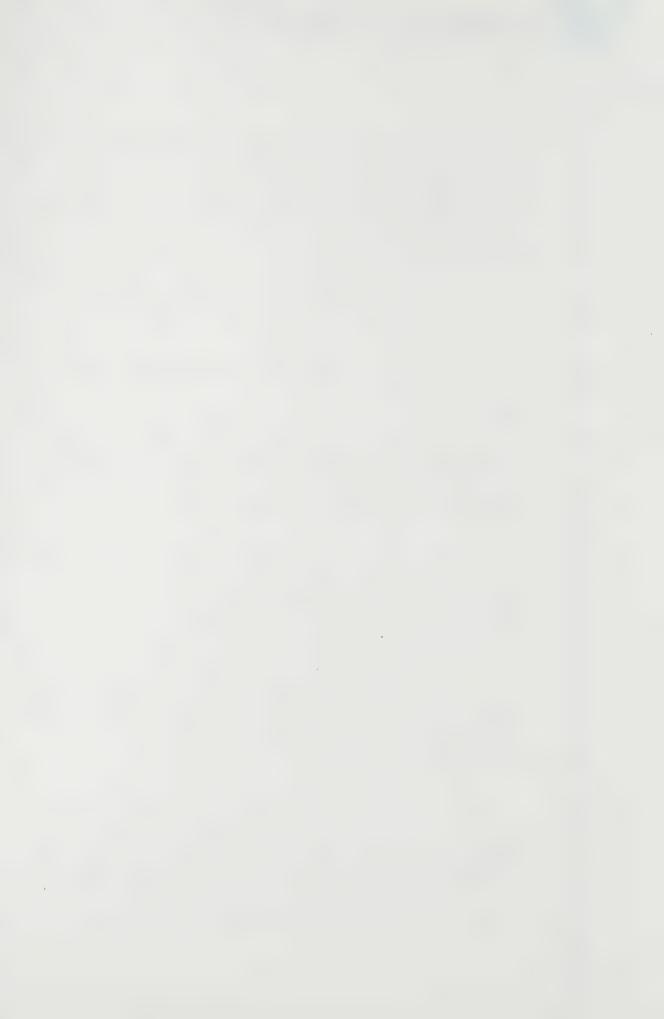
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bacteria overgrows, or, you know, you contaminate it
when you cut into it, into that area. So, it would
be analogous to when blood was drawn from an arm, you
know, you sterilize it before you draw the blood.

- All right. 0.
- It's the same sort of thing.
- I'm sorry?
- You know, it is the same kind of reason.
- Q. All right. And that is done, as I understood your evidence, Doctor, for the purposes, or at least when a sample is being taken for culture?
  - A. Yes.
- All right. And is it felt that that sterilization process reduces the risk of bacterial contamination of the sample?
  - Yes, I would think so.
- All right. And was that form of Q. sterilization in fact undertaken with respect to Kevin Pacsai before that sample was taken?
  - Yes. A.
  - All right. And you told Ms.

Forster as well that when the cultures that were sent on Kevin Pacsai came back they were in fact negative?

That is correct, yes.





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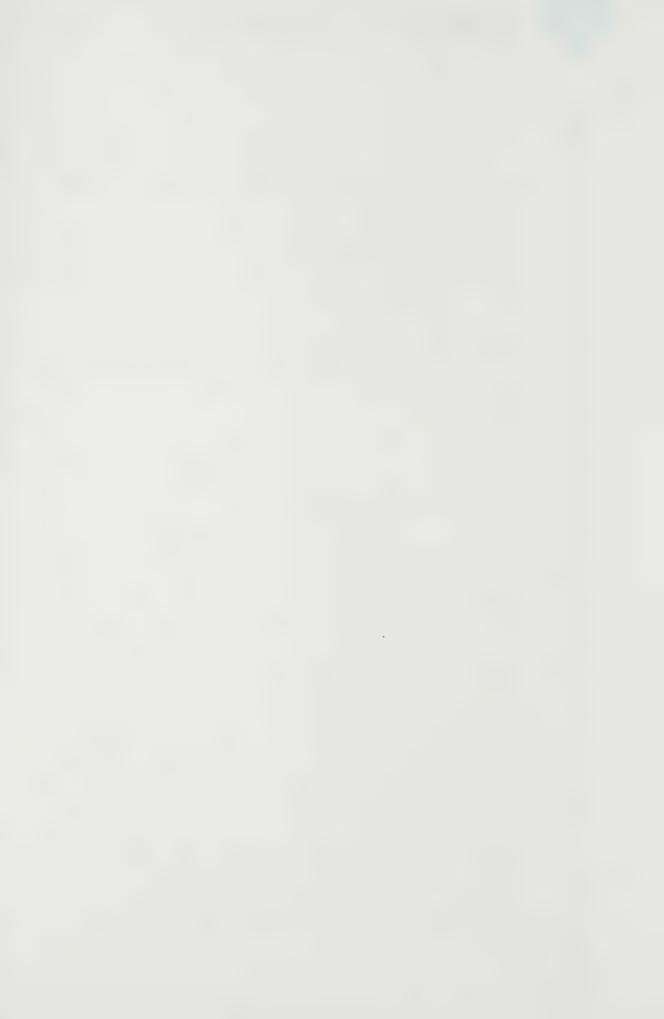
Q. All right. Would you agree with me, Doctor, that based on those two factors, first, that that sterilization technique was used with respect to that sample for the purposes as you have outlined and, secondly, that the cultures when actually tested were negative, but those two factors in combination make it improbable that that sample on Kevin Pacsai was contaminated by any bacteria in the air?

A. Yes.

Q. Thank you, Doctor. Thank you for your patience, Doctor.

Oh, there is one final matter, Mr.

Commissioner, and I hope it is something to which my friends have no objection. During the course of my discussions with Dr. Cutz he informed me with respect to the case of Allana Miller that the neuropathological tests that had been done as part of the autopsy on Allana Miller had in fact been in part carried out by Dr. Becker. His evidence before you, sir, was that the results came back essentially negative, that there was nothing significant in that report and he has provided me now with a copy of the report. It is entitled "Neonatal Neuropathology Check List". Unless my friends have any objection I propose to ask





Dr.	Cutz to	o iden	tify	the	e report	and	have	it	mark	ed	at
this	stage	while	he	is	available	to	ident	ify	it	for	us

THE COMMISSIONER: Yes, all right. It is difficult for them to indicate that without seeing it first I would think. However --

MS. CRONK: Is that the report, Doctor, which you received from Dr. Becker, being the results of the neuropathological testing on Allana Miller?

THE WITNESS: Yes. This would be actually a rough sheet.

MS. CRONK: Q. All right. And that you received from Dr. Becker?

A. Yes.

Q. All right. Is there a more formalized report in complete form?

A. There should be a typed one.

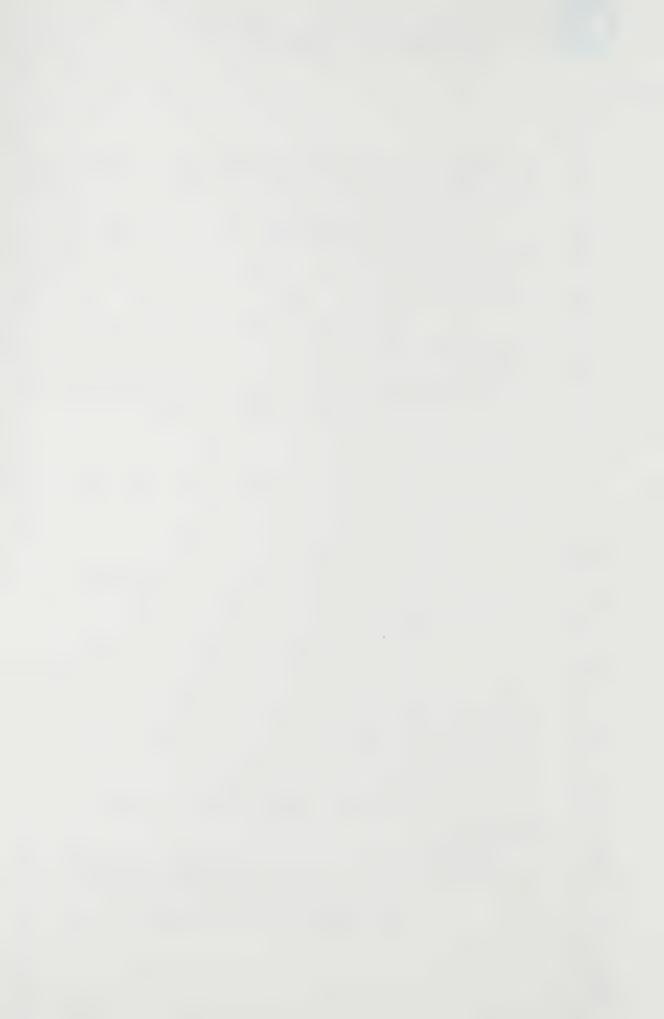
Q. Perhaps through your counsel you can provide that to us if you have a copy of it but for the moment, sir, I would ask that this be marked as it is the only material that has been provided to me.

THE COMMISSIONER: Yes, all right,

Exhibit 208.

--- EXHIBIT NO. 208: Document entitled: Neonatal Neuropathology Check List".

THE COMMISSIONER: All right.



MS. CRONK: Doctor, thank you very much for your patience.

THE COMMISSIONER: Yes.

MR. TOBIAS: Mr. Commissioner, I am sorry to make this request but I have some short questions, I would be less than five minutes, arising directly out of the territory covered by Miss Cronk in her re-examination.

THE COMMISSIONER: Yes, all right. I don't want to make a habit of this, Mr. Tobias, you know what the rules are.

MR. TOBIAS: Yes, I am aware of the rules, Mr. Commissioner, and I have no intention of making a habit out of it. You will note that this is the first time I have made such a request.

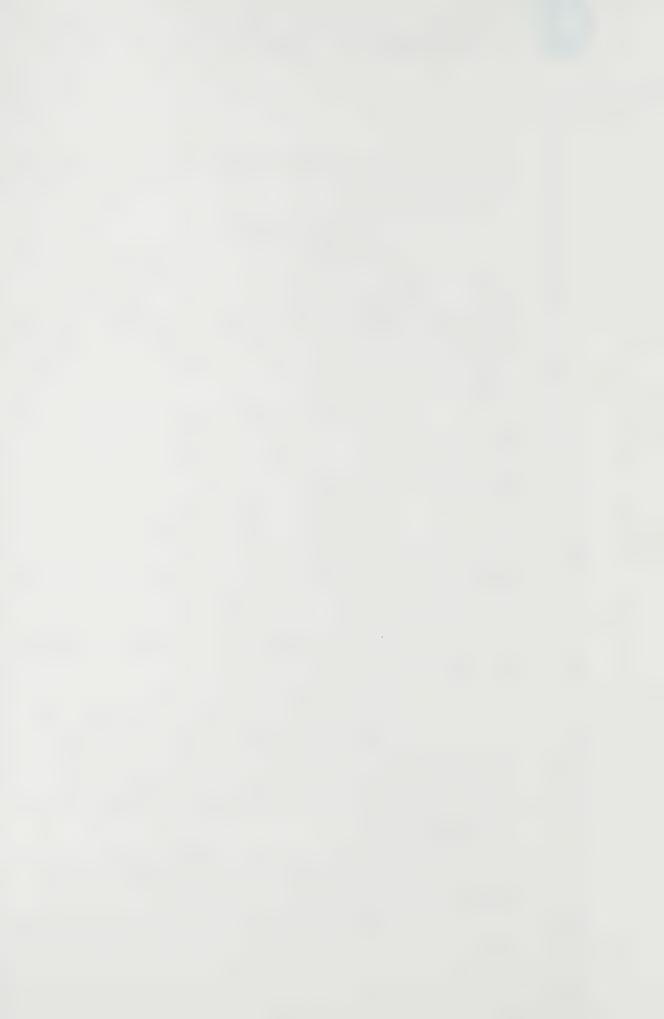
THE COMMISSIONER: All right. All right, yes, okay, carry on, Mr. Tobias.

MR. TOBIAS: All right, thank you, sir.

THE COMMISSIONER: I don't want you to, just because we are a half an hour to the regular break, I don't want you necessarily to drag yourself out to that point.

MR. TOBIAS: No, I promise you that I won't, Mr. Commissioner.

THE COMMISSIONER: You realize of course



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that after that I have to nod, I hope just nod, in the direction of the three counsel.

MR. TOBIAS: Yes, I realize that. That is the reason for my tentativeness and my apology because of that practical problem.

THE COMMISSIONER: I just want to say that was the reason for my bad temper.

MR. TOBIAS: That's fine.

## FURTHER CROSS-EXAMINATION BY MR. TOBIAS:

On. Cutz, I intend to ask just several short questions dealing primarily with something that arose on Miss Cronk's questioning about apnea and arose with respect to the Commissioner's questioning. You indicated that apnea is really the cause of why you would see evidence on autopsy of hypoxia. Do I understand that correctly?

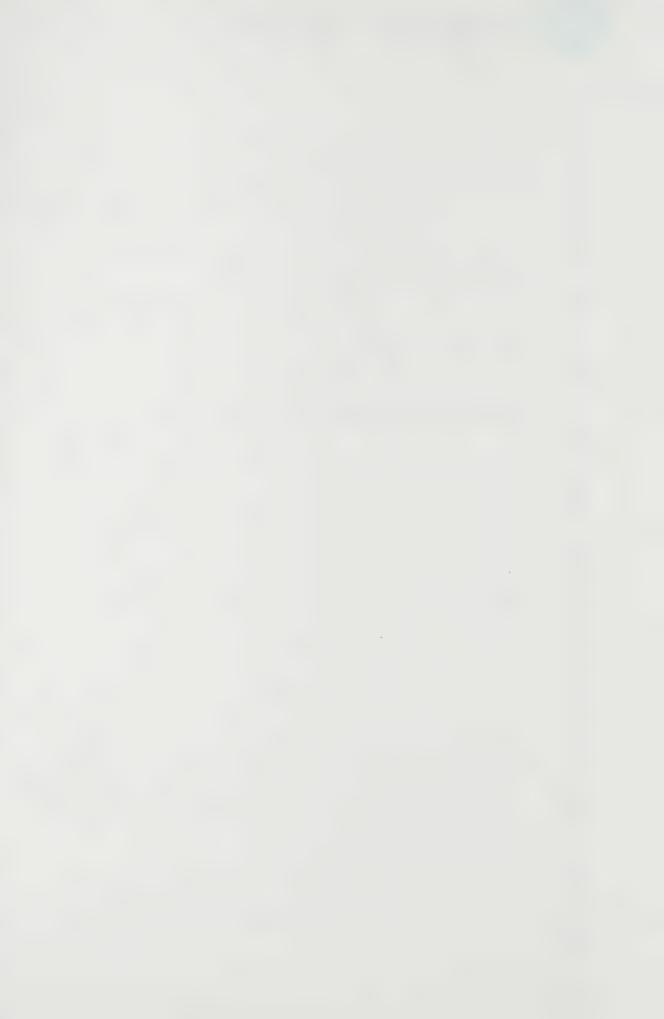
A. That is correct, yes.

Q. All right. Now, you also indicated to Miss Cronk that if one found evidence of hypoxia on autopsy without there being any clinical evidence whatsoever of apnea, one would have to assume that there were apneic periods that were unobserved.

Do I understand that as well?

A. Yes.

Q. Now, in a situation where you





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have observed periods of apnea and you find brain stem scarring, is it fair, or would you as a pathologist assume that the brain stem scarring is explained by the apneic periods even if the apneic periods took place within two weeks of death?

A. Yes, I think you could try to tie these two things together, yes. But as I mentioned before you need some minimum time before you start to see these changes.

Q. All right. Well, let me go back just for a moment. If you saw signs of hypoxia without any observed periods of apnea during life, what conclusion would you draw?

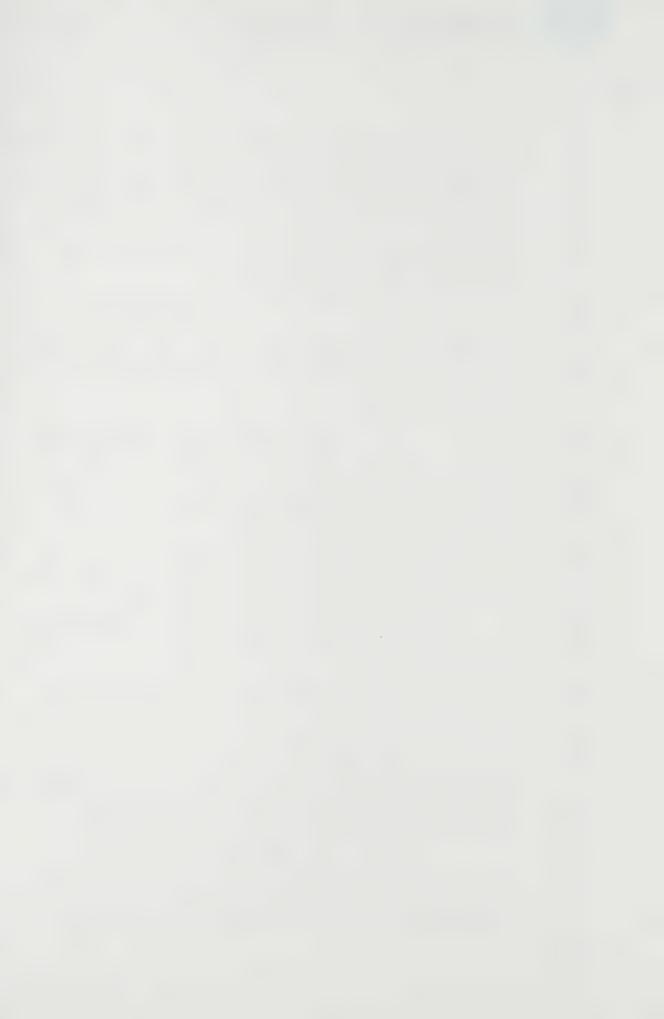
THE COMMISSIONER: How do you mean by signs of hypoxia? You mean if you saw this ---

MR. TOBIAS: On autopsy, at post mortem examination.

THE COMMISSIONER: You saw damage to the brain stem?

MR. TOBIAS: Well, brain stem scarring and thickening of the pulmonary arterials and persistence of brown fat, those are the particular markers.

Q. If you saw all of those on autopsy but they were absolutely - there was nothing in the medical record to indicate that there had been





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an observed period of apnea, what conclusion would you draw?

A. Well, I think what you are referring to would be a case which a pathologist would classify as Sudden Infant Death Syndrome or crib death.



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Q. Yes.

A. This is not uncommon that these things are not observed. The babies appear perfectly normal. These abnormalities usually occur during sleep or that is what the hypothesis is.

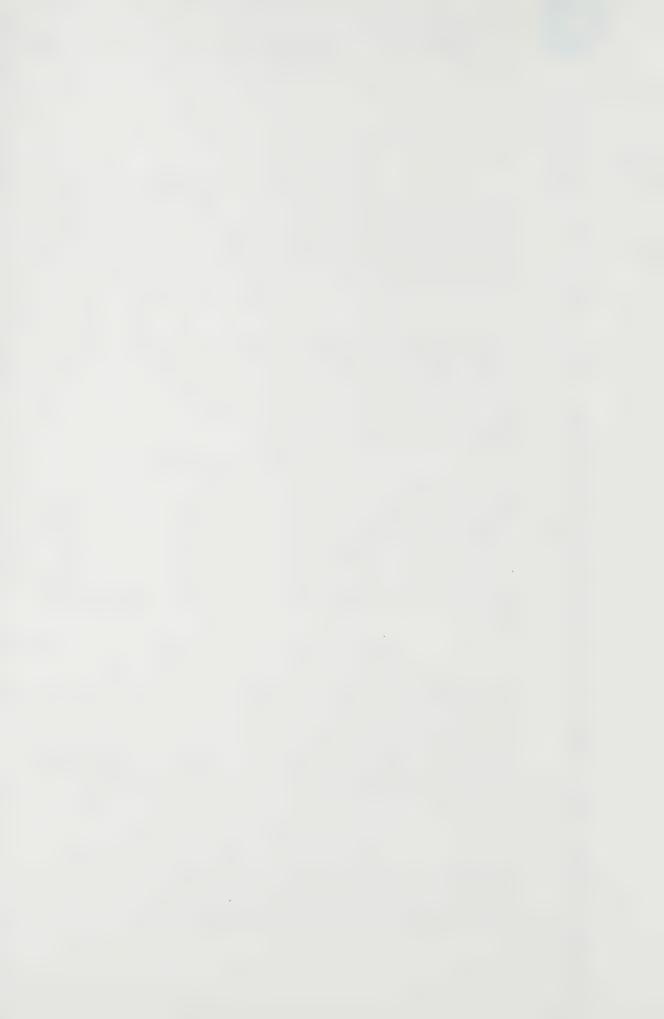
Q. All right. Are you indicating therefore that you could draw a conclusion of crib death without making an assumption that there had been unobserved periods of apnea, or would that be implicit in your diagnosis?

A. Well, if the baby and all the remainder of the history and the findings would point to the diagnosis of crib death, and you would find evidence of hypoxia on these various organs that would strengthen your diagnosis as being crib death.

Q. All right. What I am specifically asking you, though, is this: in coming to that diagnosis of crib death would you be implying in your own mind that there had been some periods of apnea that were simply not observed?

A. That is correct.

Q . All right. Now you also indicated I believe in answering Miss Cronk's question that the various indicia of hypoxia which



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are commonly seen in crib death and which Dr. Naeye identified is not something that is universally accepted.

Do you agree with that?

A. Yes.

Q. All right. If you saw evidence of hypoxia in a child and there had been periods of apnea during life, would that in your opinion be sufficient to support the pathological diagnosis of crib death? In the absence of any other pathological explanation for death I should say?

A. Yes. I think that would be a primary diagnosis.

Q. That would be your primary diagnosis? Now is that not because crib death is a diagnosis of exclusion?

A. That is correct.

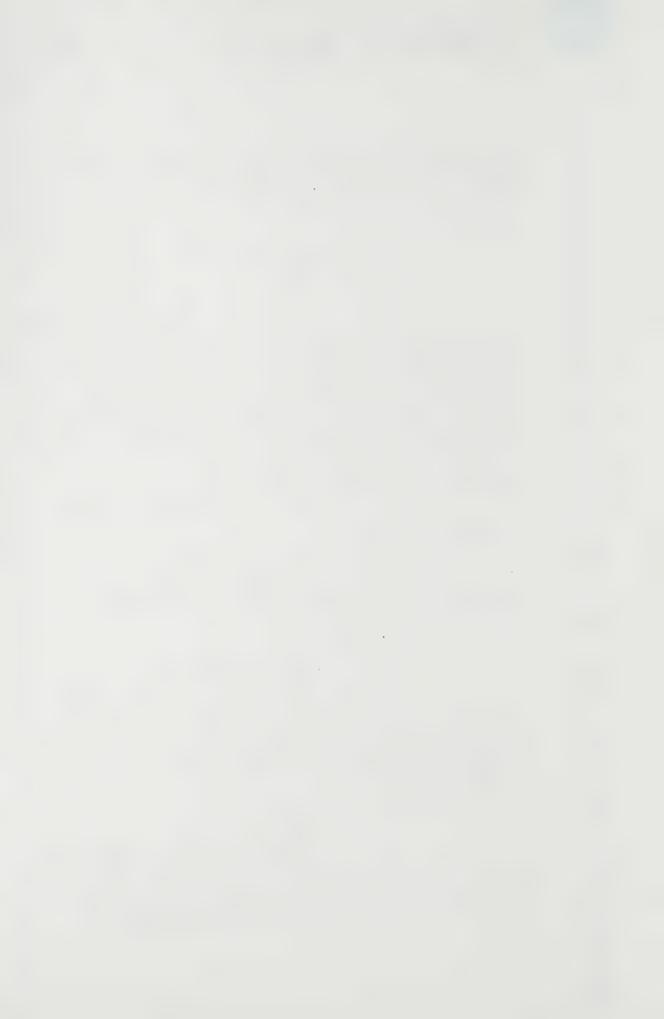
Q. And I have given you in my question, I have asked you to assume that there was no other indication of any other cause of death.

Is that correct?

A. Yes.

Q. So that would be a very large part of the reason for your coming to that diagnosis?

A. Yes, I think it kind of



depe	ends	on	the	exte	ent	and	detail	of	the	exan	ninati	.on
and	the	exp	perie	ence	of	the	person	per	forr	ning	it.	

Q. Well let me ask you this directly: let's take the same identical example,
Doctor, where there were observed periods of apnea,
and there were the various pathological indicia of crib death.

A. Yes.

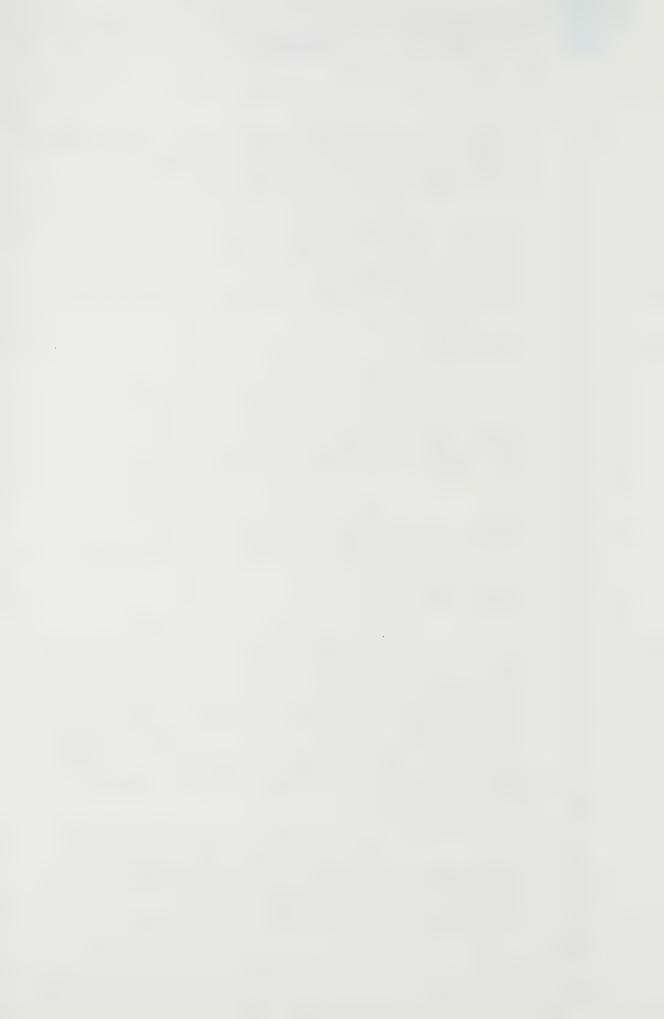
Q. You also saw evidence of chronic heart failure. Would that cause you not to make a diagnosis of Sudden Infant Death Syndrome?

A. Well, you would have to explain the reason for chronic heart failure. One possible reason could be chronic, quite profound chronic hypoxia.

Q. Did I say - I am sorry,

Doctor, I think I have confused the issue by saying chronic heart failure. If you in that example also saw pathological evidence of congestive heart failure, would that cause you to go away from the diagnosis of SIDS because you had found another pathological cause for death?

A. Well, I think the classical crib death the patient is just found dead. There is no medical or other observations.



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enti	rely	•	I a	ım	ask	ing	you	to	mak	e a	an as	sur	mptio	n,
and	the	ass	ump	ti	on	is	that	you	ı ha	ve	the	hyp	poxia	

A. Yes.

- you have got observed periods Q. of apnea and you as well have pathological evidence of congestive heart failure.

Now in that particular example you have the other explanation. You haven't excluded all other explanations. Would that cause you to go away from the diagnosis of Sudden Infant Death Syndrome?

Not necessarily because you Α. have cases where it is called an aborted SIDS where the child is resuscitated.

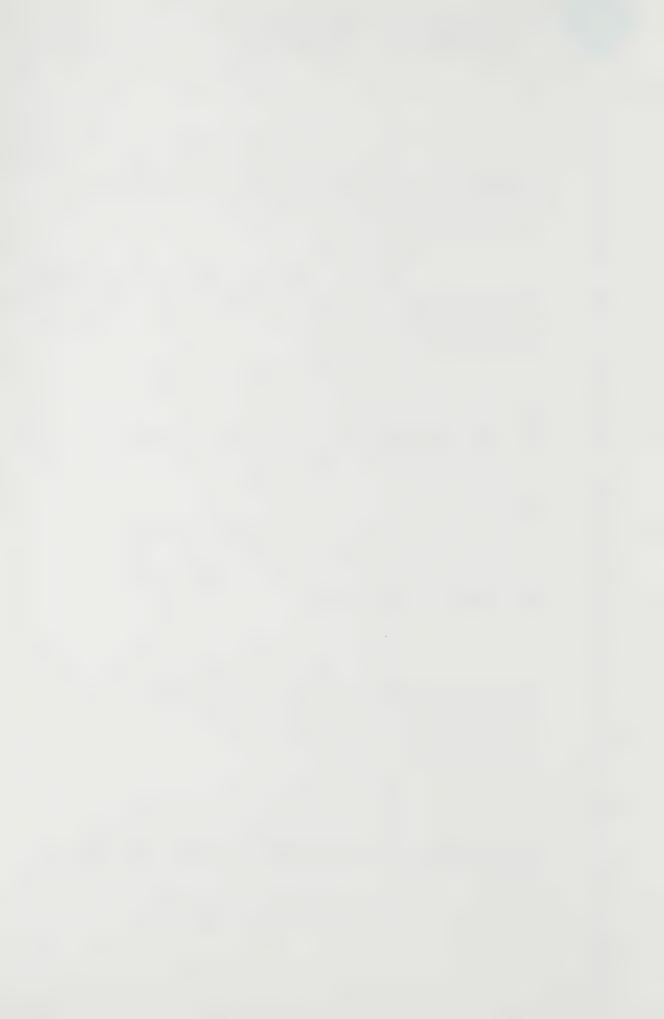
> 0. Yes.

And then because of the resuscitation and the damage suffered during the sort of period between life and death you develop complications.

> 0. Yes.

Α. And this is due to the complications and has nothing to do with the crib death.

> All right. Are you Q.



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indicating ---

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So this would be, you know, A. would not be relevant to the basic disease. This is something related to the treatment received after resuscitation.

All right. I want to make sure, Doctor, that I understand what you are saying. Again looking at my particular example you are saying the evidence of congestive heart failure might be explained by a previous episode of heart failure and resuscitation efforts?

- That is correct. A.
- So you could explain it 0.

away?

- Yes. Α.
- My question specifically is Q. this, Doctor, and again I realize it is difficult because I am asking you to make certain assumptions that you might not see in a pathological setting. But just for the sake of argument, please, assume that you could not explain away the congestive heart failure by evidence of previous heart failure and resuscitation. Let us assume that it wasn't there and that there was no other way to explain away why the chronic failure was there or the



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congestive heart failure was there, would you then
agree with me that it would be much more difficult
to come to a diagnosis of Sudden Infant Death
Syndrome because there was another pathological
anatomical cause of death present?

A. Well, as I say, you know, it depends on the criteria one uses to make Sudden Infant Death Syndrome.

Q. That is precisely what I am asking you.

- A. Yes.
- Q. Is one of the criteria absence of any other cause of death?
- A. Well, but it is also the way the child or the infant presents.
  - Q. I understand that.
- A. And once there is some kind of a medical intervention or something then it doesn't rule out that the child suffered from Sudden Infant Death Syndrome.
- Q. Yes, Doctor, and assuming there was no medical intervention.
- A. Yes. Then you wouldn't have any records of this as to what happened, and if you find evidence of heart failure then you wouldn't call



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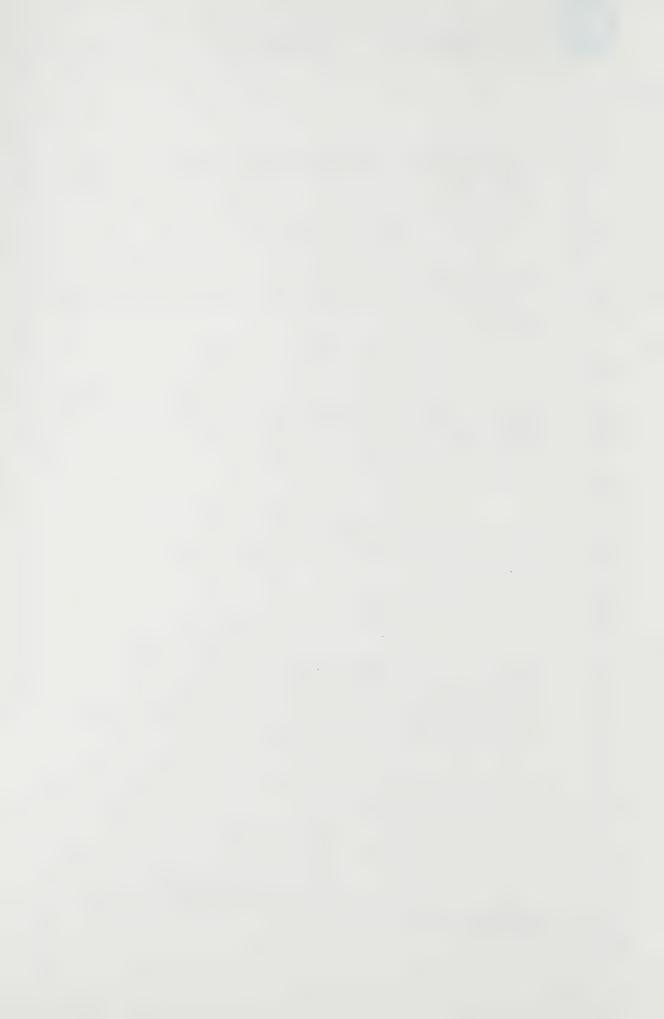
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it crib death. You would have to explain it some other way.

> 0. All right. Fine.

Now if you had a situation, Doctor, where you had the episodes of apnea observed during life ---

- Α. Yes.
- 0. - it would be fair to assume from that there may have been episodes of apnea during life that were not observed?
  - Α. Yes.
- 0. Okay. If you have observed periods of apnea, a history of difficulty in breathing ---
  - Α. Yes.
- 0. - and evidence of chronic hypoxia, do you agree with me that not every pathologist would accept that as conclusive evidence of Sudden Infant Death Syndrome?
- A. Well, we would - we at Sick Kids certainly accept that.
  - Q. That is fine.
  - A. Yes.
- But I am going back to your Q. statement before.





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A. Yes.

0. That it is not universally accepted by pathologists everywhere. That was your evidence, was it not?

Α. Well, this is a scientific debate discussing the results obtained.

Exactly. And not everyone Q. agrees with the conclusions that you draw from that debate?

> That is right. A.

0. Is that correct?

Yes, so there are certain people who draw conclusions based on their own experience.

> All right. 0. Fine.

A. And who may or may not agree with the study.

MR. TOBIAS: Thank you very much,

THE COMMISSIONER: Mr. Roland?

MR. ROLAND: I haven't heard anything that I didn't already know from Dr. Becker so I have no questions.

MR. ORTVED: I have no questions.

THE COMMISSIONER: Miss Cronk?

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MS. CRONK: No, sir.

THE COMMISSIONER: All right. Thank you, Doctor. Thank you very much, for the second or third time.

Do you want to take a break now?

MS. CRONK: That is fine.

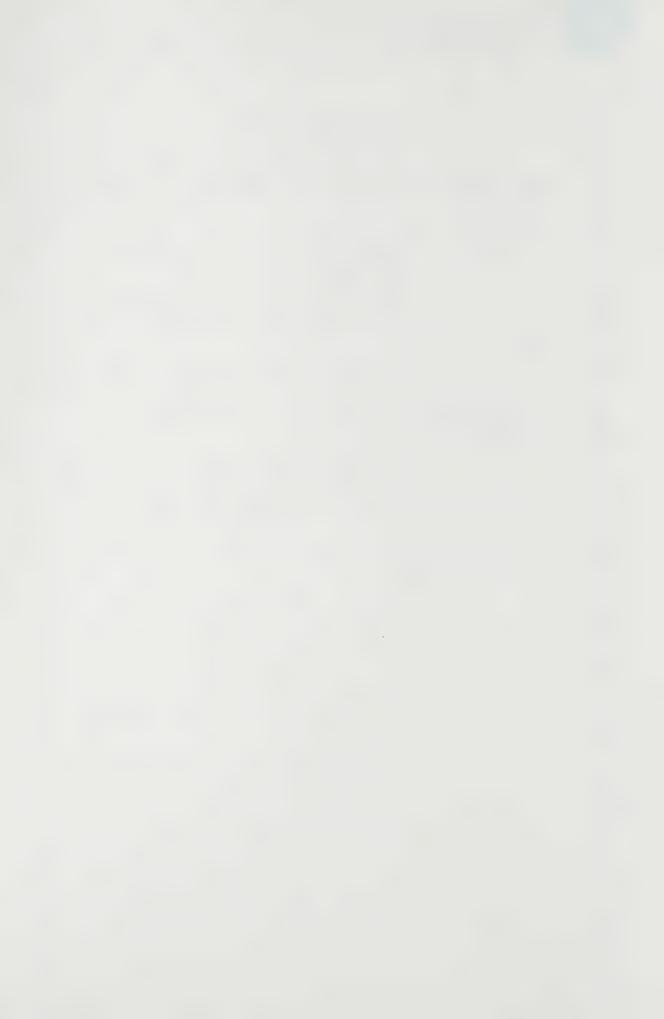
THE COMMISSIONER: Well, it is to suit

you.

MS. CRONK: If we can take it now we can proceed right through to one o'clock, and I am content that we do that.

THE COMMISSIONER: Yes. Well, I think it might be wise if we take 20 minutes now.

---Short recess.



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--- on resuming.

THE COMMISSIONER: Yes, Miss Cronk. MS. CRONK: Mr. Commissioner, our next witness is Dr. Graham Ellis, who, as you recall, previously testified before you.

Dr. Ellis.

## GRAHAM ELLIS, Recalled

## DIRECT EXAMINATION BY MS. CRONK:

Dr. Ellis, you were pre-Q. viously sworn in this proceeding and you are still under oath today, sir.

> Α. Yes.

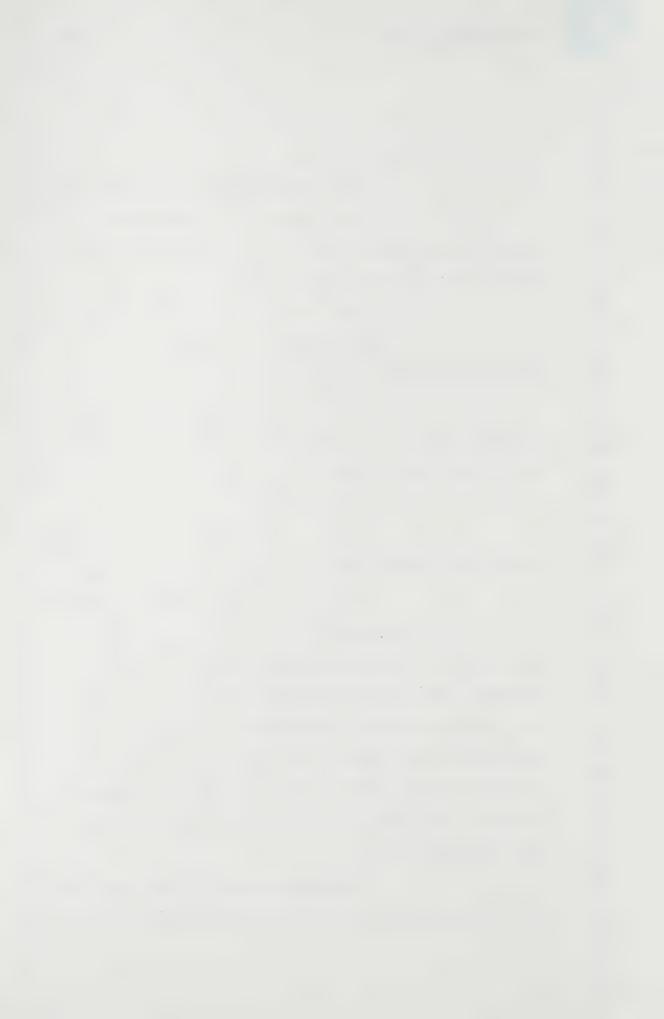
0. Dr. Ellis, there are three areas that I would like to discuss with you today.

The first is the general contents of the digoxin books which, we understand, were maintained in the Biochemistry Laboratory at the Hospital under your supervision during the period of time when you were responsible for the digoxin assays that were being conducted and, as well, the contents of the various clinical chemistry computer printout forms that we have been reviewing since you last testified.

The second area is your involvement by way of supervision of various digoxin assays

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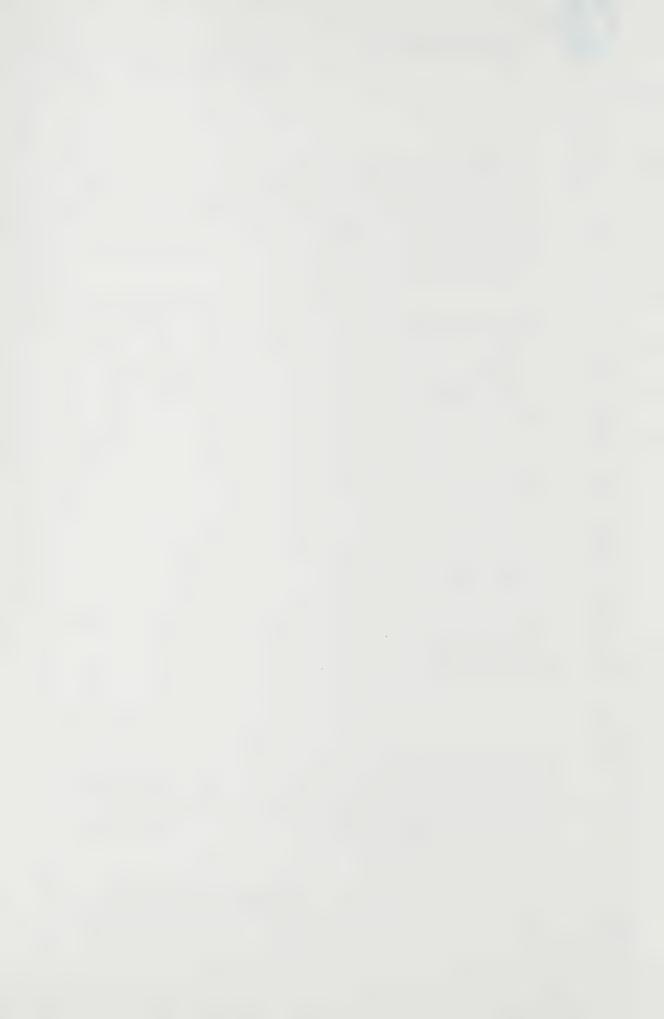
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that were conducted on specific children in the timeframe with which we are concerned; July of 1980 to March 1981, in respect of blood serum samples that were tested for digoxin.

Then, the final area is, again your involvement by way of supervision or otherwise on digoxin assays that were conducted on either tissue samples or body fluid samples from those various children, again during the same time period.

Dealing first, doctor, with the issue of the contents of the digoxin books maintained in your laboratory, as I understand it and to refresh perhaps everyone's recollection, you previously testified that during the period 1980 to the end of March 1981, you were responsible for the radioimmunoassay for digoxin at The Hospital for Sick Children. Do I have that correct?

- A. That is correct, yes.
- Q. And the technique you previously told us was used during that period to conduct any and all digoxin assays that were performed at the Hospital.
  - A. Yes.
  - Q. Do I have that correctly?
  - A. Yes.



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Q. Doctor, I would ask you to turn to Exhibit 32B.

And, perhaps, Mr. Registrar, you could provide a copy to Dr. Ellis.

Doctor, this volume is a compliation of a number of exhibits that were introduced in evidence at the preliminary hearing in The Queen vs. Nelles, and I would ask you first to turn to Tab 45 of that book, which, as I understand it, is one of the digoxin books maintained in your laboratory which was marked as Exhibit 45 at the preliminary hearing. This particular book is expressly to cover the time period from January 13, 1981 through to March 25, 1981.

Can you identify this as one of the digoxin books maintained in that time period in the laboratory, doctor?

A. Yes. This is a copy of that book.

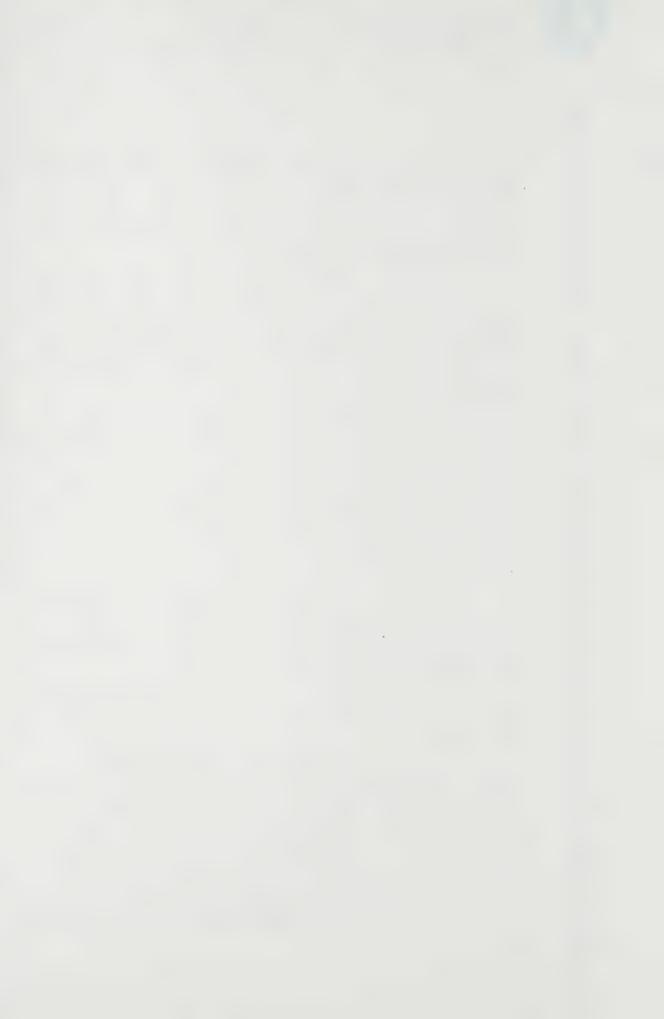
MR. TOBIAS: Pardon me, Miss

Cronk. Was that Exhibit 47 at the preliminary hearing?

MS. CRONK: Exhibit 45, I believe.

MR. TOBIAS: If it is the same as what you have handed out this morning, it is 47.

MS. CRONK: It is not, Mr. Tobias.



of all, sir.

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You have the wrong document in your hand. Exhibit 32B, Tab 45, which was also Exhibit 45 at the preliminary hearing.

THE COMMISSIONER: Has everyone not got a copy of that exhibit?

MS. CRONK: Everyone has a copy.

THE COMMISSIONER: Everyone had except me, until today, and now I have it.

MS. CRONK: The greatest oversight

MR. ORTVED: I wonder, did you have to pay as much for it as I did? I got a bill with mine!

MS. CRONK: Q. Doctor, I would ask you, first, after you finish sympathizing with Mr. Ortved, to turn to the cover page of Tab 45.

A. Yes.

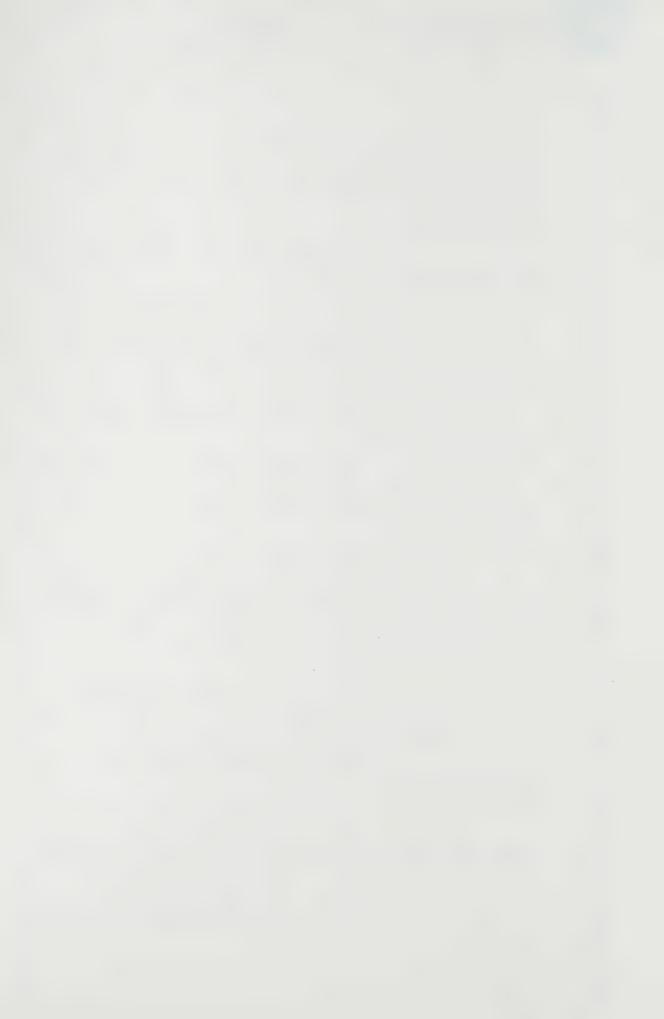
 $\Omega.$  We see there, first of all, the numbers "393" encircled.

Could you explain what those numbers refer to?

A. I believe this was the code number for the entry of digoxin in the computer.

Q. At the Hospital?

A. At The Hospital for Sick



Children.

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Q. Can you help me, doctor. Whose responsibility would it be to record in this digoxin book, or any others like it which we will see in a few moments, the results of any digoxin assay that had been conducted in the Hospital?

A. It would be the technologists in my section.

Q. And would you, as part of your responsibilities in overseeing the technologists, have occasion on a daily basis to review the assay results that had been entered in the digoxin book?

A. I would have occasion -I would have opportunity to read these on a daily
basis. It would frequently be my practice, but I
cannot say that every day, vigorously, I read these.

Q. I take it, though, very often you did?

A. Yes.

Q. And in respect of the exact contents of these books, do I take it, because of the code numbers which appear on the book, the 393 for digoxin which you have told us is the computer number for digoxin assay, that only assays performed in respect of the drug digoxin would be entered in



these books?

correctly, yes.

the case.

A. Yes. I believe that to be

Q. Would you turn to the very first page, then, doctor, if you would - it is unnumbered. It is the first page behind the cover page.

This, doctor, is a photocopy of the inside cover of the actual digoxin book for this time period. Once again, we see the code number for digoxin, "393", and we then see the first entry at the top of the page, an entry which I take to read "Specimen should be drawn 0800 hours, preferably never before 0600 hours".

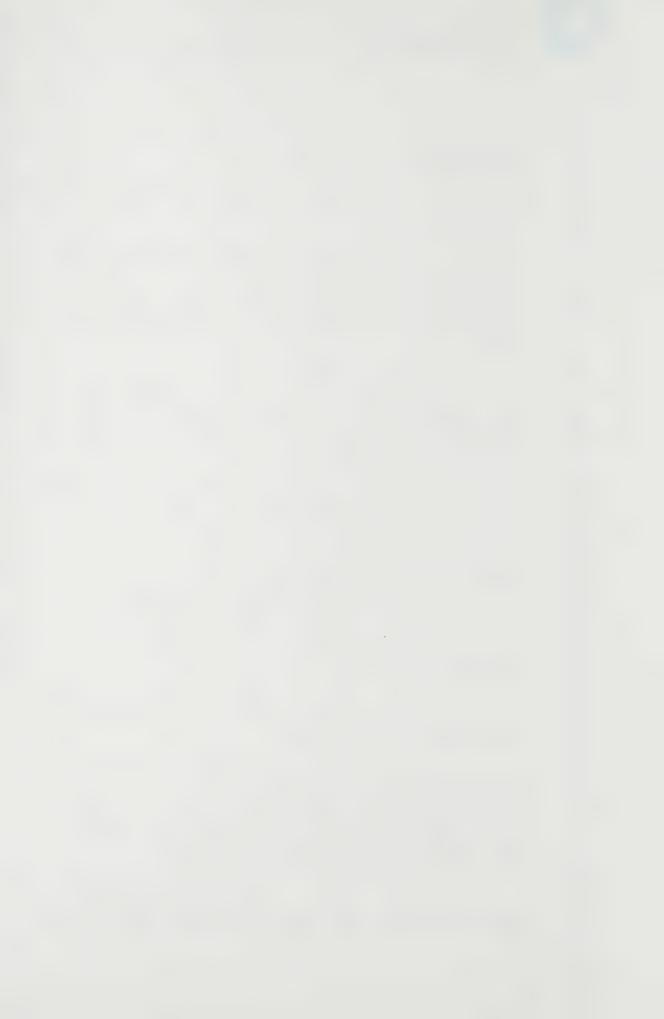
Have I read that correctly?

A. You have read this

Q. Can you help me, doctor, as to what that refers to?

A. This refers to the desirability of obtaining digoxin samples eight hours after the dose of digoxin has been given and, preferably, not before six hours.

Q. So, we should probably then, doctor, as you understand it, be interpreting



that entry to mean, not that the sample should be drawn at 8:00 a.m., 0800 hours --

A. Yes.

Q. -- but, rather, that it should be drawn eight hours after the last dose has been administered; is that correct?

A. That is correct.

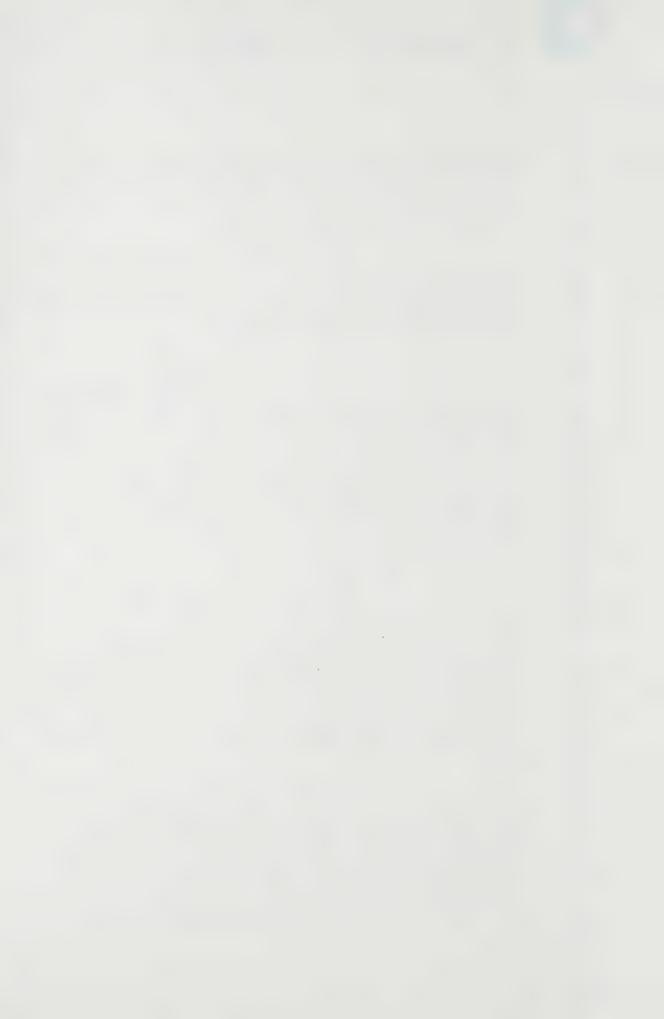
Q. And similarly, we should probably be reading the end of that entry as meaning, not that the sample should never be drawn at 6:00 a.m. but, rather, it should never be drawn before six hours after the last dose of digoxin has been administered?

A. Yes.

Q. Doctor, do those two indications accord with your understanding as it then was during this timeframe, July of 1980 to March of 1981, as to what the optimum conditions were for the drawing of the sample for purposes of a digoxin assay?

A. Yes, they would. On very rare occasions, we may go to five hours, but we try to avoid that, if at all possible. Six to eight is regarded as the best time.

Q. Thank you.



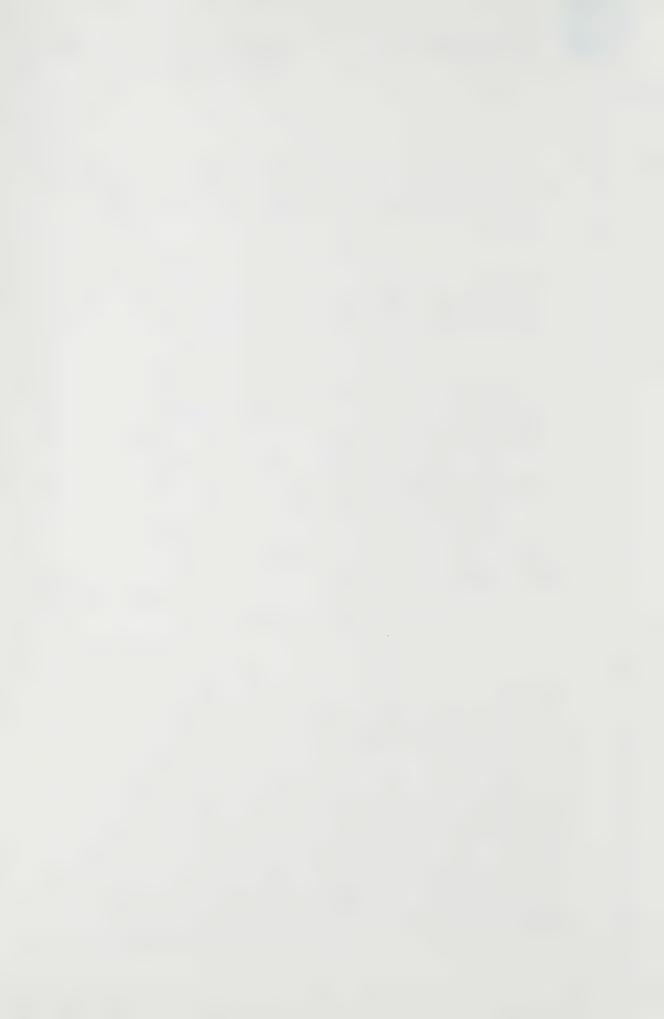
Doctor, do you know who made the entries, these particular entries, in the digoxin book?

A. I don't know, but the writing is -- I think it looks like one of my technologists'; Mrs. McKellar, possibly.

O. Doctor, the next entry
on the page reads, "1.0 to 1.8 maintenance level
greater than 2.5 - a toxic level", and on the top
left-hand side of the page, we see the short form
for nanograms per millilitre. We have heard, in
prior evidence - and simply to repeat it now - I
take it that all results recorded in this book
were measured in nanograms per millilitre and recorded
on the basis of that unit of measurement?

A. Yes.

Q. Can you help me, doctor, in terms of your understanding, because you recall that you have given previous evidence in respect of the therapeutic levels of digoxin as you understood them during this time period and also as to the toxic levels, was it your understanding during this period - that is, this book covers January 13, 1981 through to March 25, 1981, was it then your understanding that a maintenance or therapeutic level of



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digoxin would be 1.0 to 1.8 nanograms per millilitre?

A. I think I gave evidence on this before. My own interpretation would be, as indicated in the Resident's Handbook, with the various ranges that are indicated there.

I am trying to remember how this might have got -- I am trying to speculate as to how this might have got into this book. I believe it was transferred from a previous book which was older than this one, but I think you indicated to me that it wasn't in the immediate predecessor of this book.

Q. Now, doctor, before that gets terribly complicated and to be fair to you, the evidence -- your previous evidence, as I understood it, when you testified originally in these proceedings was that you considered the applicable ranges to be 0.5 to 2.5 nanograms per millilitre as optimal therapeutic range.

Do you recall that?

- A. Yes.
- Q. And that you considered 2.5 nanograms per millilitre to 3.0 as being an area of overlap?
  - A. Correct.
  - Q. And that you considered



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anything greater than 3 as being overdigitalized or toxic, although, even at 2.5 nanograms, you would be a little bit concerned.

Do I have your evidence correctly?

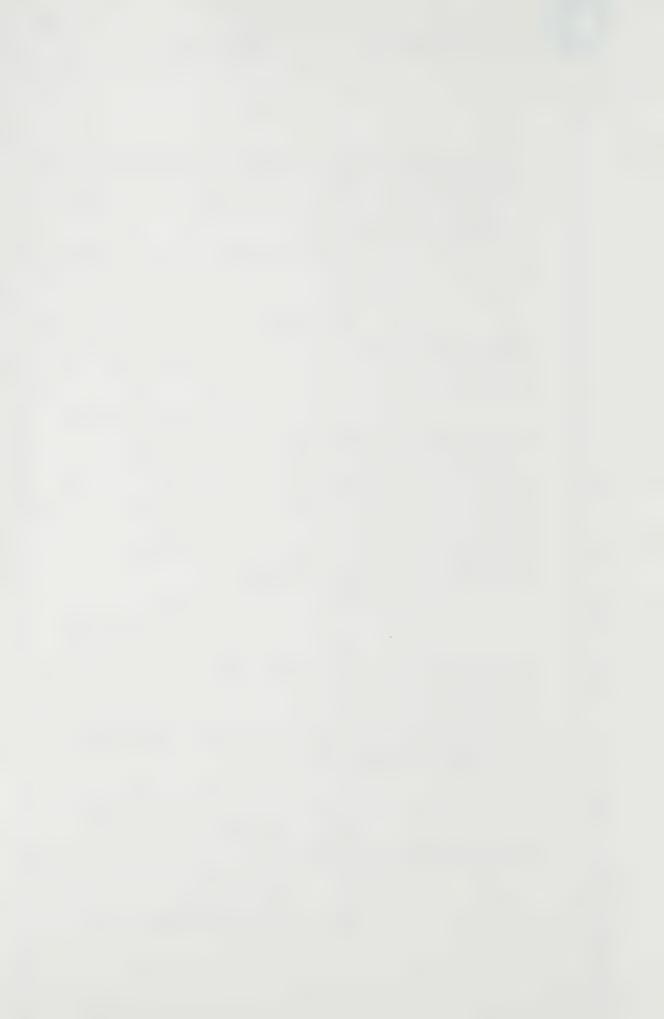
Yes. That is a summary.

MS. CRONK: That, Mr. Commissioner,

appears at Volume 6, page 907, of Dr. Ellis' evidence.

I take it then, doctor, 0. that whoever made these entries and for whatever reason, the maintenance levels described there are not the ones which, in your view, were being treated as the appropriate therapeutic ranges in your laboratory during this time period?

- A. Yes, that is correct.
- Q. Similarly, with respect to the toxic level of greater than 2.5, with regard to your previous evidence, I take it you would have no difficulty in agreeing again that anything over 2.5 would cause you some concern?
  - Α. Anything over 2.5, yes.
- Although it might not 0. necessarily be a toxic level in any particular case?
  - Α. Yes.
  - Thank you, doctor. Q.



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Finally, doctor, we see the entry, "Low result report under 0.2".

Could you again explain for us briefly what that means?

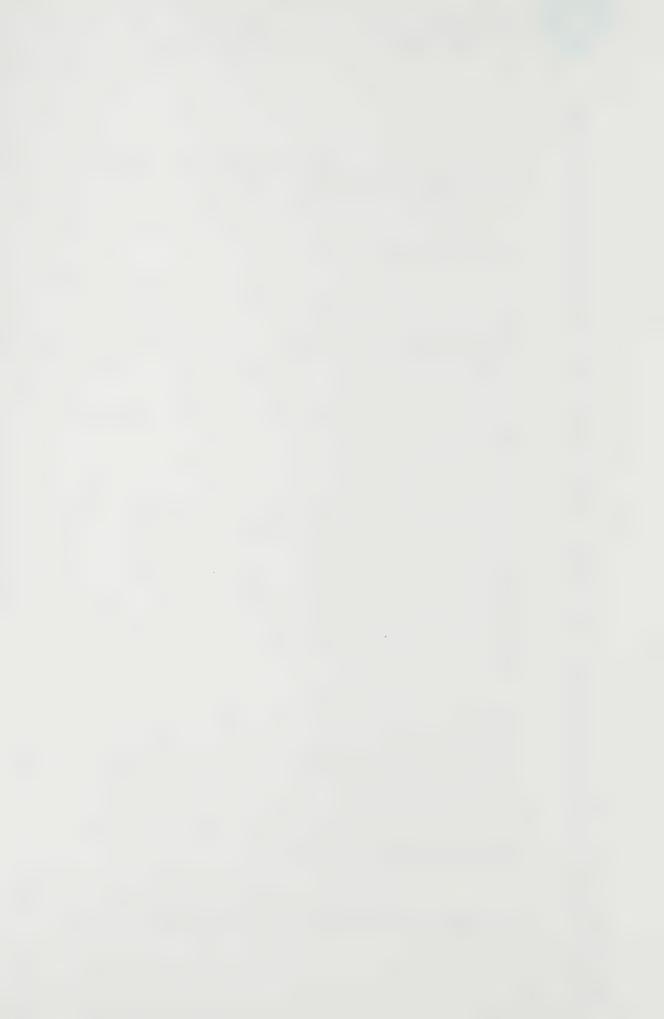
A. This just explains that, when this note was written, it was the policy of the Department not to report results if the calculated result was under 0.2. In other words, if the result came to 0.1 or 0.05, the result of 0.2 would have been produced.

Q. And to put that into context, doctor, as I recall your previous evidence, you testified, again during the time period that we are concerned with, that the minimum detection level used at that time in your laboratory for digoxin assay on the radioimmunoassay method was set at 0.2?

A. I recall going into great detail as to how difficult it was to set a detection limit. For the convenience of reporting, that figure of under 0.2 was used in my laboratory at this time.

 $\Omega$ . That was, then, the minimum detection level?

A. No. I am saying this was the level that was used, the lowest level that was



reported.

 $\Omega$ . Thank you, doctor. Anything over that, I take it,

would be reported at the actual number that had come out as a result of the assay that you conducted?

That is correct.

Doctor, could you turn 0. then to page 2, which is the immediate next page, at Tab 45.

Do you have that?

Α. Yes.

Can I also point out that, in addition to this information that was contained within the digoxin book, a photocopy of the Resident's Handbook with all the ranges contained therein was available to my staff for access and for any telephone enquiries immediately after the production had gone to that book.

So, I take it that if there Q. was any confusion in their minds as to which ranges applied, they could first have recourse to this book, the digoxin book itself?

For the actual results.

0. For the results but, also, for the indication of what the levels were?

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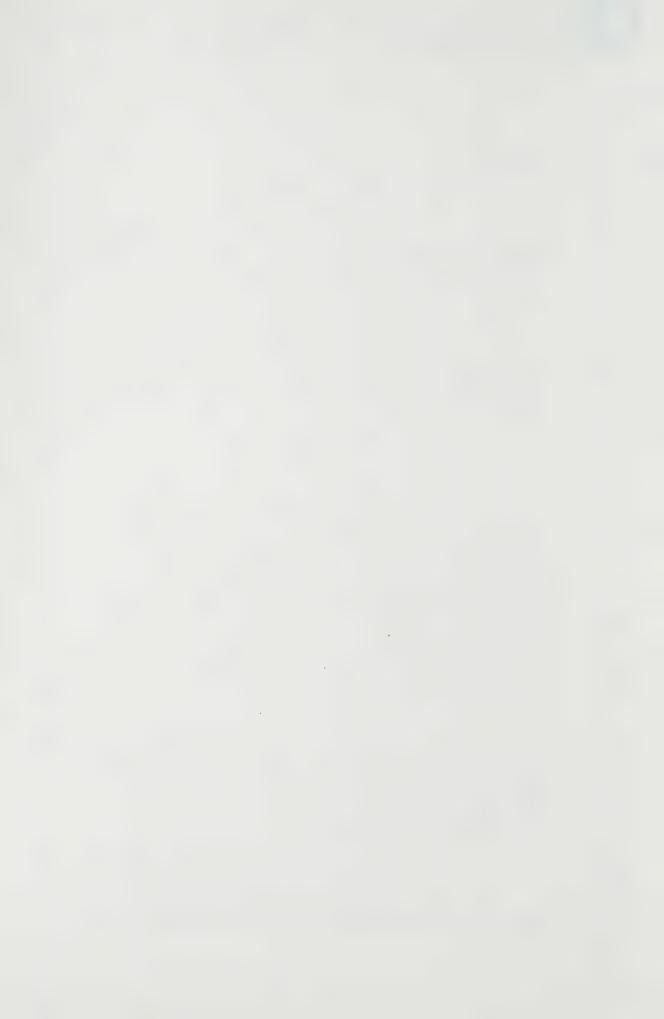
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They would have -- the

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A. No.

Α.

 $\Omega$ . I'm sorry?

indication of what the levels were would be contained in the photocopy of the Resident's Handbook, Biochemistry Section, that was available to them after the Biochemistry Handbook was printed.

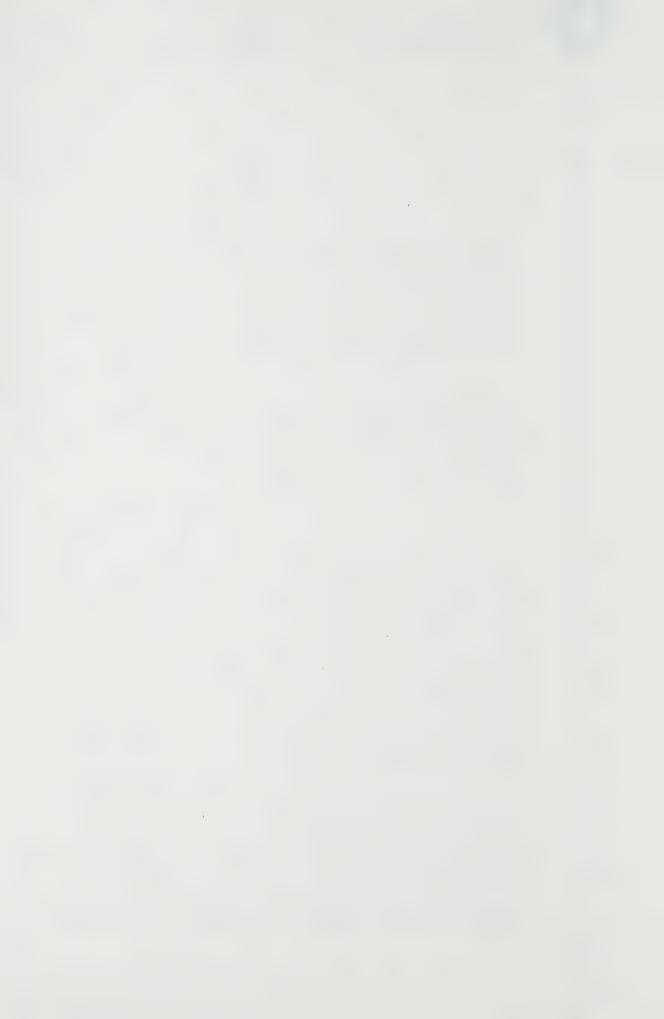
Q. And they could, as well, in addition to having recourse to the Handbook itself, of course, discuss the matter with you if there was any confusion in their minds?

A. Yes, that is correct.

 $\ensuremath{\mathbb{Q}}_{ensuremath{\bullet}}$  Doctor, then, on page 2, if you would, we have, as you will appreciate, during

the course of evidence introduced subsequent to your own, we have had occasion to look at these digoxin books and the various entries contained in them, and I am going to ask you, in certain respects, to confirm our understanding as to how some of these entries should be interpreted.

First of all, on page 2, you will see the date of "January 15, 1981". There is no magic in my turning to this particular page, doctor. Would we be correct in interpreting that date as meaning the date upon which the assay itself was



conducted?

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A. Yes.

Q. Then, doctor, on the left-hand side of the page, the first column, we see what we have been interpreting to be the names of the various patients upon whom digoxin assays were conducted from various samples.

A. Yes.

Q. Then, in the second

column, doctor --

A. Well, in the first column, there is a series of letters.

Q. I'm sorry, you are quite right - the second column over.

Well, what do the letters refer to?

A. The letters refer to the number put on the tubes during the batch.

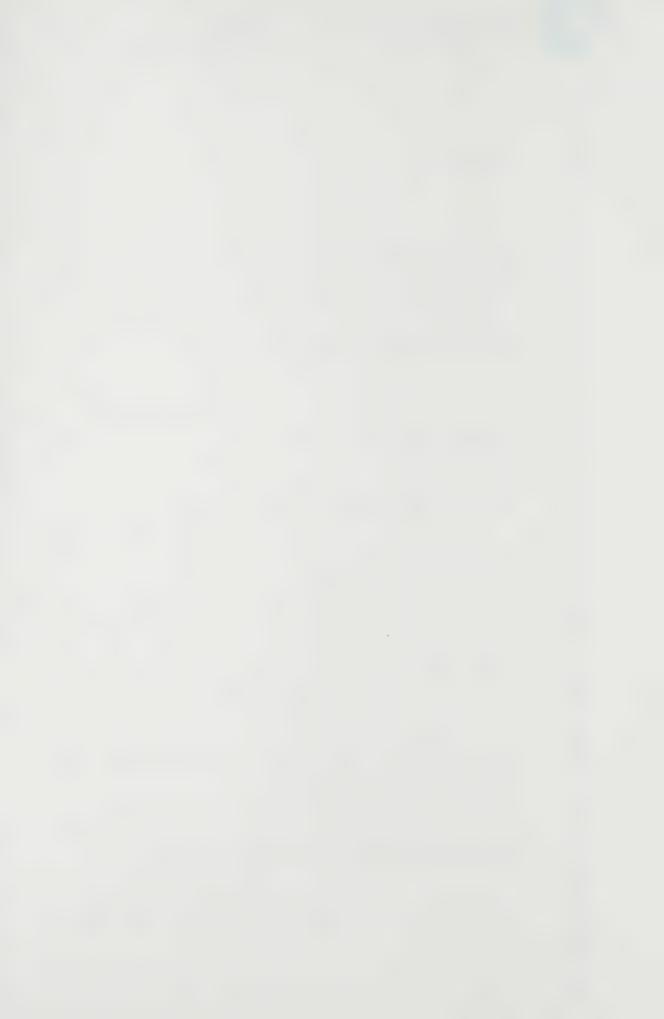
THE COMMISSIONER: I'm sorry?

THE WITNESS: The number that was written for that particular batch on the tubes as the assay was processed.

MS. CRONK: Q. That was the method of segregating the various tubes?

A. Yes.

THE COMMISSIONER: They seem to



Ellis dr.ex. (Cronk)

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be alphabetical, too?

THE WITNESS: Yes.

THE COMMISSIONER: So, I take it it is the order they come in? Is that the idea?

THE WITNESS: It is the order in which they are run in the batch.

THE COMMISSIONER: I don't think
I quite understand that. Presumably, one would
come in that would have a vial, or whatever it is
they have the blood in.

THE WITNESS: Yes.

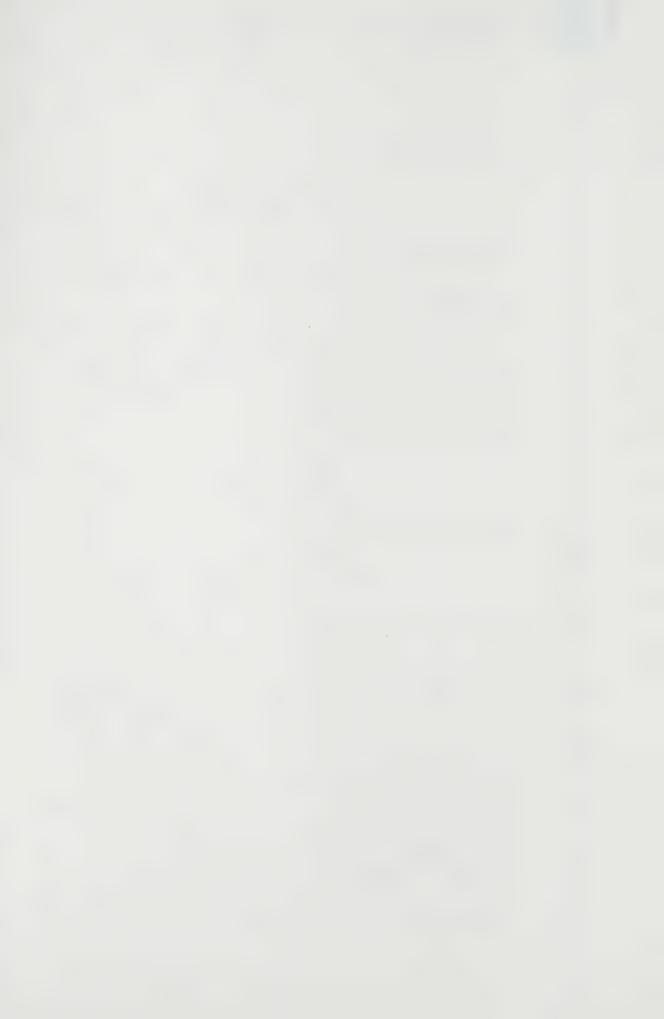
THE COMMISSIONER: It would have the name of the child.

THE WITNESS: Yes.

THE COMMISSIONER: And you would give it a letter, would you?

THE WITNESS: No. We would give it a letter at the time of start of the analysis.

MS. CRONK: Q. Doctor, let me ask you this: If a number of samples arrived in the laboratory at the same time, or virtually simultaneously, how are the entries in respect of those samples recorded in this book? Are they recorded in the order in which the assays are conducted or are they recorded in the order in which



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the samples are received?

In the order in which Α. the assays were conducted.

Q. All right. Thank you,

THE COMMISSIONER: The order in

which?

doctor.

THE WITNESS: The order in which the assay is conducted.

THE COMMISSIONER: Yes.

MS. CRONK: Q. Doctor, then you have indicated, quite properly, that the second column contains patient names.

> Α. Yes.

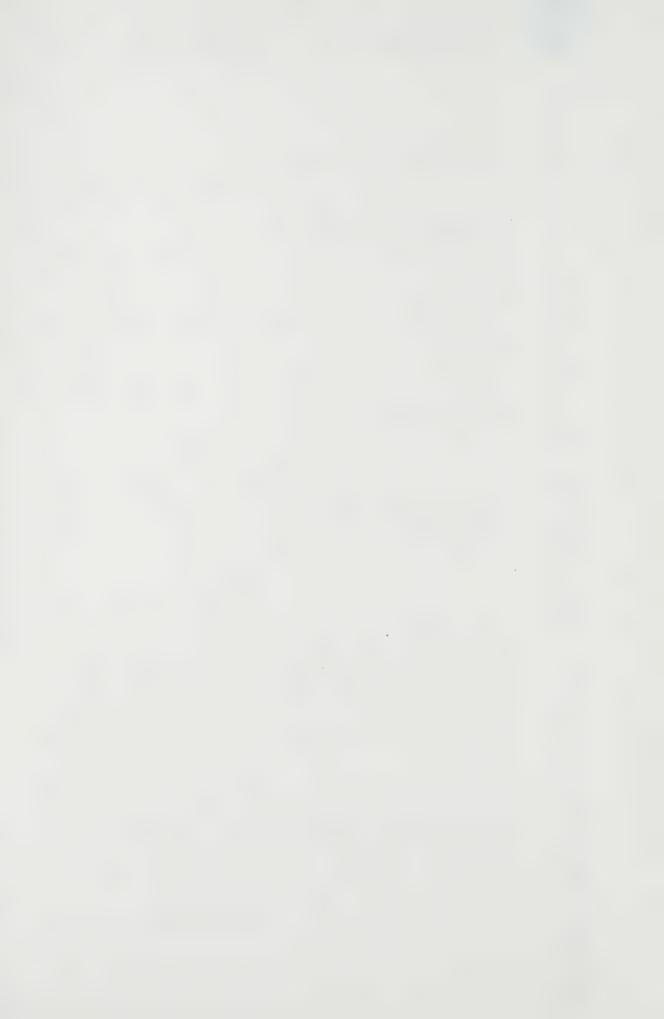
Q. Then, there seems to be a space beside the patient names and the next immediate column for entry of information and, in some cases, we see some descriptive comment pertaining to the sample that is involved; do we not?

> Α. Yes.

Q. And then the next column, doctor, on this particular page, for example, under Item or Specimen C , we see the word "pathology".

> Α. Yes.

Q. "Path", which we take to



G17 2

mean "pathology"?

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And then, in respect of 0. others, an indication of the number of wards.

Yes.

Can you tell me, doctor, what the information contained in that column was intended to mean?

Α.

This is the source of Α. the request and the destination to which the report should be sent.

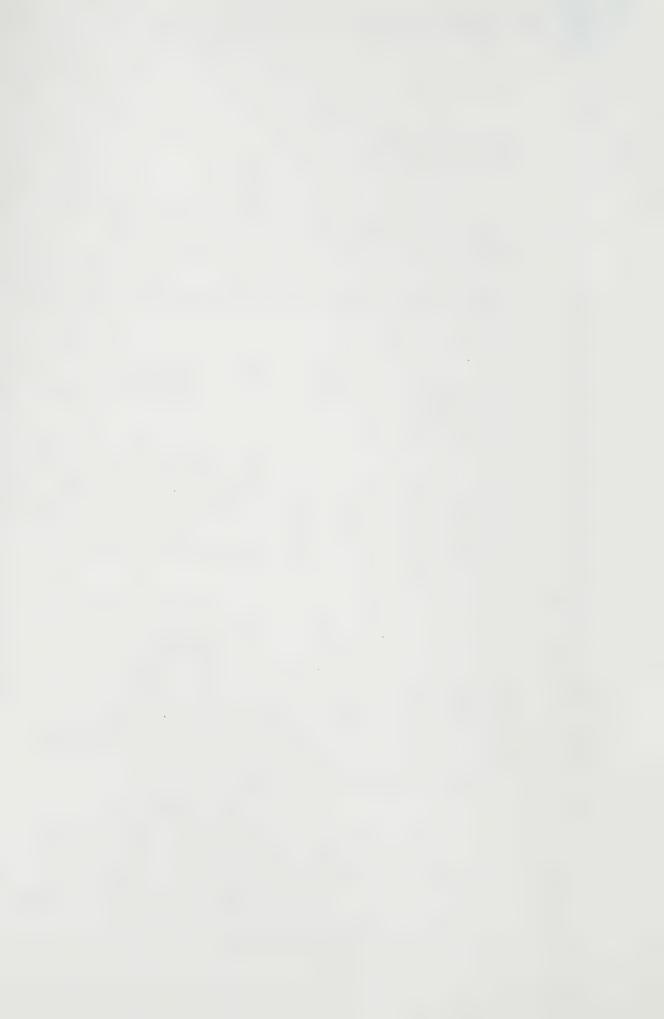
So I take it then, if the Q. sample was received from Pathology and was to be, the results on that sample were to be reported back to Pathology, that is the entry that would be made in this column?

> Α. Yes.

Q. And similarly, if a request came in from the ward, the requesting ward would be identified in this column and that is who, in the first instance, would be the recepient of the results once available?

That is correct.

And then, doctor, the next column we see a short form for various dates. Can you tell me what the information in that column refers to?



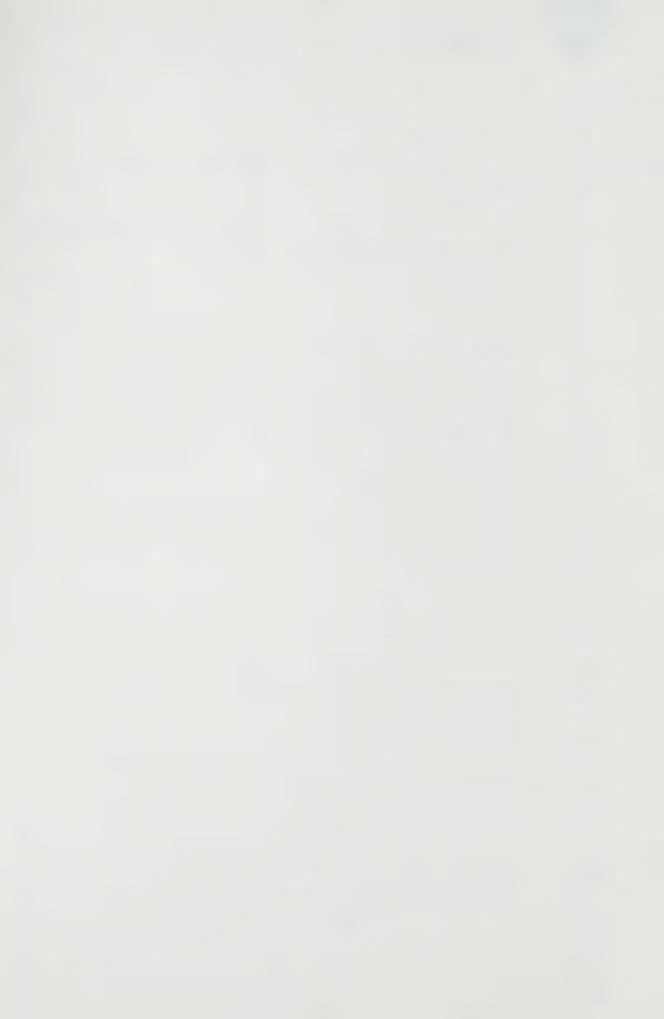


G18 2 Α. specimen. 3 Q. 4 the specimen was actually collected? 5 Yes. Α. 6 0. 7 sorry, doctor, just back to the previous column. 8 Can you tell me where that information would come 9 from? Where would that be obtained, the indication from which ward or department in the Hospital had 10 requested the assay? 11 Α. 12 sample requisition that accompanied the sample to 13 Biochemistry. 14 Q. 15 A. Yes. 16 0. column, doctor, we see various times. What do those 17 times refer to? 18 Α. 19 time at which the blood was drawn on the date 20 indicated to the left. 21 Q. 22 the sample was taken? 23 Α.

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This is the date of the Is that the date upon which You are referring -- I'm This would be on the And similarly the date? And then, in the next Those times relate to the That is the time at which Yes.



G19 2

			Ç	ĵ.	And,	once	again,	where
would	you	draw	that	informa	ation	from	?	

A. In 99 per cent of cases, that information would be directly transcribed from the requisition.

Q. And if the requisition form, for any reason, was not completely filled out, or was deficient such that the time of the sample collection was not indicated, or the date of the sample collection was not indicated, what, then, would you do in your laboratory, if anything, to determine when and at what time the sample had been obtained?

A. We would probably not do anything in that, on this particular occasion, you see, the sample from Pathology, Sample C, there is nothing in that particular column to indicate the time at which it was taken.

Q. Yes.

A. And unless the result is abnormal, there is no real need for us to go and check it.

Q. And if the result was abnormal in some respect, would you then make further enquiry to determine when and at what time



the sample had been taken?

A. That could well -- yes. That could well have happened.

Q. I take it it is possible but was it the norm? Was that the policy in the laboratory, that those enquiries should be made if a result was irregular or an abnormal result was achieved?

A. Yes. I think that would be usual. Yes, pathology specimens are unusual, okay, so I am not saying that would necessarily be the case for pathology samples.

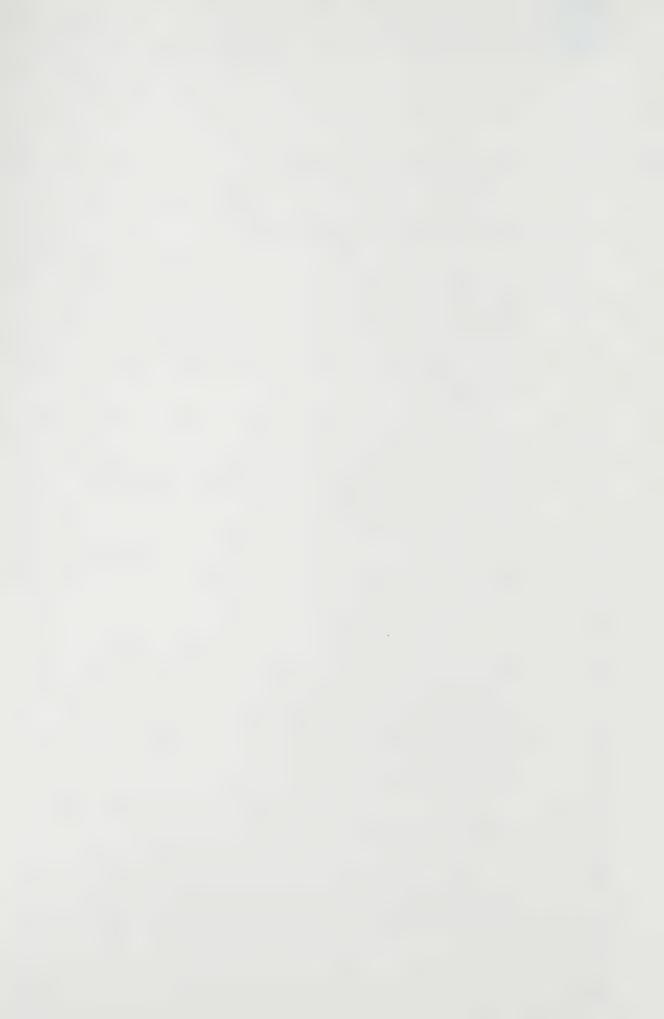
Q. Unusual in this particular sense that they were taken at autopsy?

A. Yes.

Q. So, doctor, then, throughout this book, whenever we see a dash in any particular column of information, are we then properly to conclude the information simply wasn't provided to the lab?

A. In the majority of cases, I would think, yes.

Q. Doctor, in the next column we see a number of what we have taken to be sample numbers. Does that column set out the



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number assigned to particular samples sent for assay to your lab?

A. Yes. This sample -- this number was the number on the sample requisition.

Q. Yes.

A. The sample requisition has attached to it sticky labels with the same number on them and these sticky labels are usually attached to the tube of blood taken and, so, there is a positive identification between the tube of blood and the sample requisition.

THE COMMISSIONER: Attached by whom?

You, doctor?

THE WITNESS: No, by the wards that are drawing the blood, or the person who is drawing the blood.

MS. CRONK: Q. So, those requisition forms then, I take it, are available throughout the Hospital to be completed on the ward or in the various departments if a sample is going to be taken and sent to the lab for assay?

A. Yes.



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Q. All right. So, it is not a situation where the requisition form would be filled out in a normal case in the lab itself, but rather would have been filled out at the time the sample was taken?

A. That's correct, in the normal case, yes.

Q. All right. Then, Doctor, we have seen in a number of cases that the actual numbers assigned to any particular sample are proceeded by a letter, in some cases it is G and in some cases it is H and in some cases it is J and in some cases it is D. Can you tell me, is there any particular purpose in having a different letter precede the sequence of numbers that are assigned to any given sample? Is there any significance to that?

A. There is no major significance. It indicates a different printing run of the whole batch of requisitions.

Q. Thank you, Doctor. And then finally in the last column, the second to last column, again, we see a number of initials and perhaps we can deal first with Sample No. D for a patient known as Amber Moore. We see the letter V,



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what does that refer to?

A. This refers to the fact that this was a venous blood sample, as indicated on the sample requisition.

Q. All right. Then I take it the information in this column refers to the type of sample involved?

- A. Yes.
- Q. All right. And with a V it is

venous?

- A. Yes.
- Q. All right. What is the A stand

for?

- A. Arterial.
- Q. All right. And we see on that page as well an O. What does that stand for?

A. O means that either it may not be venous or may not be arterial or the exact type of the sample may not have been indicated to us on the requisition.

Q. So, I take it then that it could mean either one of two things: either you don't know what type of sample is involved.

- A. Yes.
- Q. All right, or it is something



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other	than	a	blood	sample,	from	a	vein	or	from	ar
artery	7 •									

A. Yes, I think it basically means there is no specific indication in the appropriate location as to what that sample is.

 $\Omega$  . And the appropriate location being a place to indicate that on the requisition.

A. Being three boxes on the requisition, yes.

Q. All right. Doctor, we have also seen, although there isn't one as it appears on this page that I can immediately notice the letter C in that column. What does that stand for?

A. Capillary.

Q. All right.

THE COMMISSIONER: I'm sorry, C stands

for what?

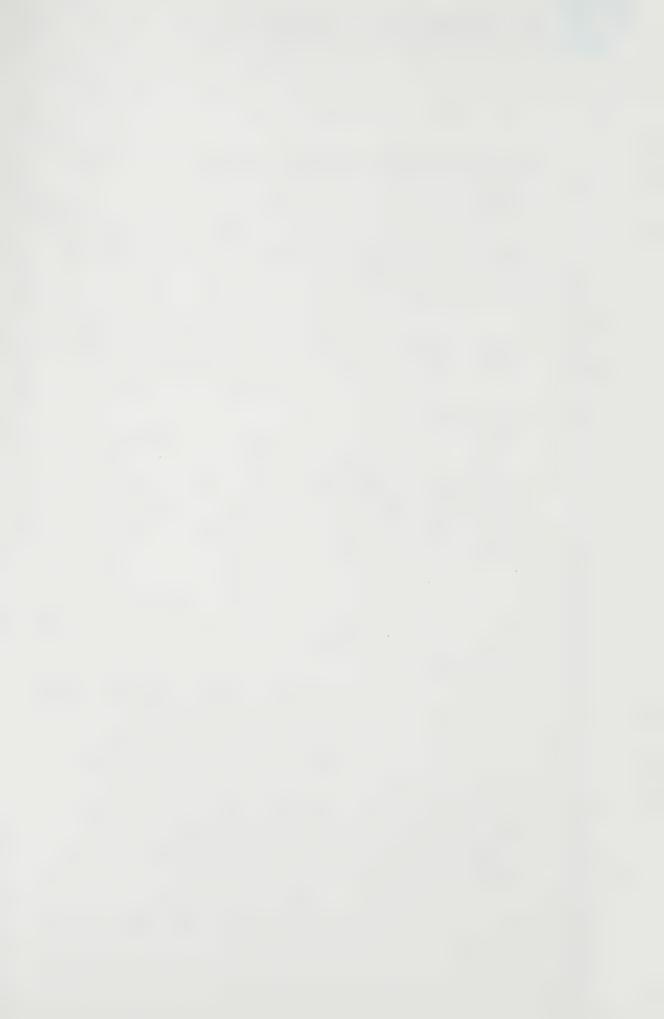
THE WITNESS: Capillary blood sample.

THE COMMISSIONER: Capillary.

MS. CRONK: Q. And then finally,
Doctor, the next column over the final column in
this particular page we see what appears to be
obvious is the result of the particular assay?

A. Yes.

Q. All right. And where numbers



appear in that context once again they are always expressed or were during this time period in nanograms per millilitre?

- A. That is correct.
- Q. All right. Can you tell me,

Doctor, what the letters RPT refer to?

A. They indicate that a result had not been produced on that particular sample and it was necessary to repeat that sample.

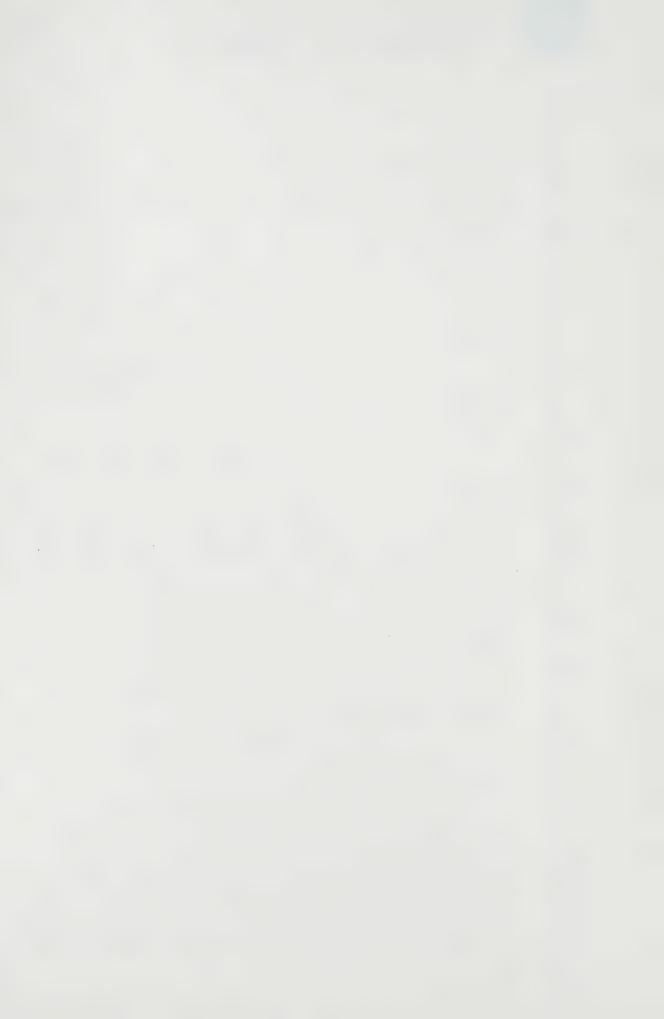
Q. All right. Does that mean,
Doctor, for example, and we will come back with more
particularity to the Estrella case, but we see RPT
beside Sample C on Janice Estrella, does that mean
that that particular sample was beyond the maximum
measurement of the assay and required further
dilution and further assay to achieve a result?

A. Are you asking if that specific sample or ---

 $\Omega$ . Generally. Generally when the letters RPT are there.

A. Generally that is one
explanation. The other explanation would be if it was our usual practise to analyze in duplicate.

If in fact the duplicates agreed badly then it would
be necessary to reanalyze that sample again to obtain



a satisfactory result.

- Q. All right.
- A. Under those circumstances we would then still put repeat in that particular box.
- Q. I'm sorry, Doctor, if you say the two duplicates agreed badly, I take it you mean that there was some meaningful discrepancy between the results on each?
  - A. Yes.
- Q. All right. And in that case you would reassay again in duplicate to see what the result was again the second time?
  - A. Correct.
- Q. All right. Doctor, we have sometimes seen as well the letters NSQ in that column. We have been interpreting them to mean not sufficient quantity, is that correct?
  - A. That is correct.
- Q. All right. And as well,
  Doctor, we have sometimes seen before a particular
  number the symbol for greater than the number that
  is involved, but we have also seen, as we see on
  Item H under January 16th the letter X before a
  number. Do you see where it says X 4.7?
  - A. Oh, yes, yes.



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All right. Can you tell me Q. what the X means?

Α. The X means the same, greater than.

All right. Doctor, we have 0. also seen a symbol which, depending on who is trying to interpret it, sometimes looks like a WO.2 and sometimes like a UO.2. There isn't one as it happens on this page but can you tell me first of all which symbol it is and, secondly, what it means?

Α. Yes. It really means under, it is U, capital U.

> All right. 0.

Α. And this is just within the laboratory for convenience. There is always a problem wherever you go in terms of less than and greater than signs. People can never remember, or this has been my experience.

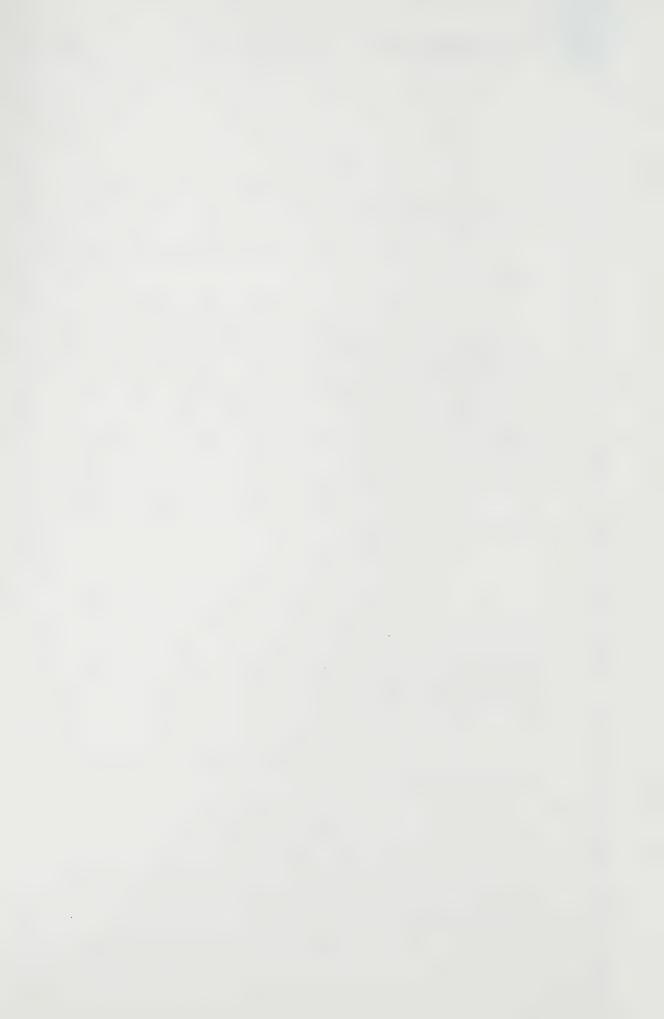
They don't think of them like 0. little arrows?

> Α. No, they don't.

I see. 0.

Or even less than is an L on Α. its side slightly.

> Well, just simply by way of 0.



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illustration, Doctor, and we will come back to this. Could you just quickly flip to page 30 of the same digoxin book. Do you have that?

- A. Oh, yes.
- Q. Sunday 22nd of March, 1981.
- A. Yes.
- Q. Now, we will come back to

some of the --- I'm sorry, sir?

THE COMMISSIONER: page 30 you said,

of what?

MS. CRONK: Page 30 covers the entries for Sunday, March 22, 1981.

THE COMMISSIONER: On what?

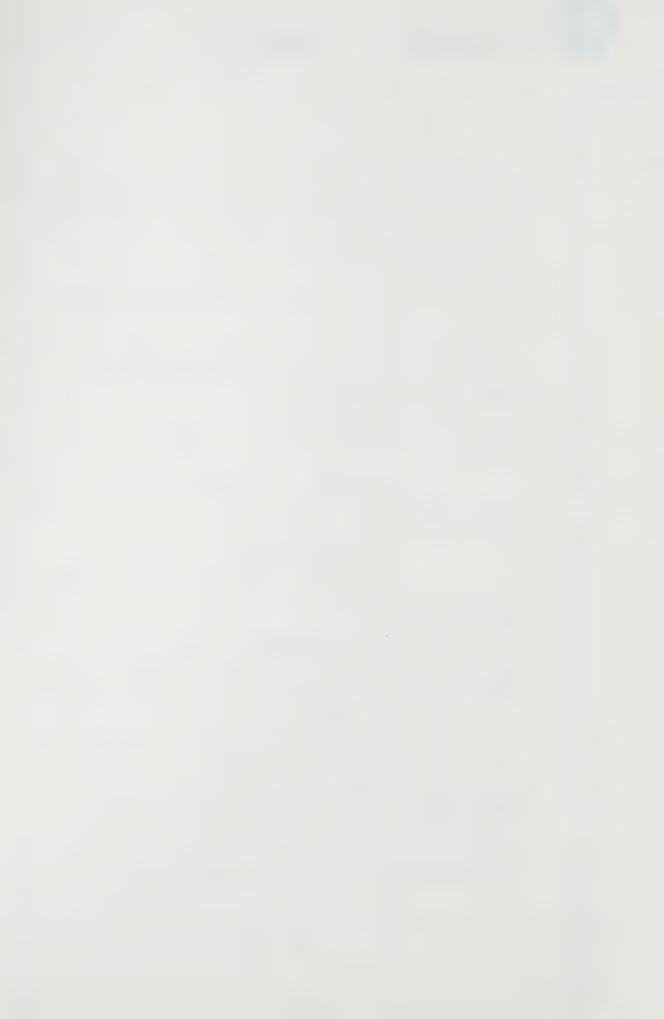
MS. CRONK: Still the same tab, sir.

Still Tab 45.

THE COMMISSIONER: Oh, I see, I managed to skip into Tab 46, I'm sorry about that.

MS. CRONK: I see.

- Q. We will come back to these entries later, Doctor, with respect to the particular results and the entries that are recorded, but if we look for example under Item No. 13 through to Item 16 on page 30. Do you see that?
  - A. Yes.
  - Q. All right. We see there the



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result, and I confess I can't tell whether it is a W or a U 0.2, but I take it that you are now telling us that that is a U?

- A. Yes.
- Q. And it stands for under?
- A. Under.
- $\Omega.$  So that if we were to look at those readings it would be under .2 or under 0.2?
  - A. Yes.
  - $\Omega$ . All right, Doctor.
- A. And that would be the entry put in by our keypunch people into the computer.
  - Q. A 'U'?
  - A. A 'U' or an 'X'.
  - Q. All right.
- A. And the computer would then produce not U or X but less than or greater than, appropriately.
- Q. Thank you, Doctor. Mr. Registrar, could you show Dr. Ellis if you would Exhibit 106, which is the medical record for Kevin Pacsai.

Doctor, could you turn please to page 83. Do you have that, Doctor?

- A. Yes.
- Q. All right. Doctor, this



Report - The Hospital for Sick Children", and it appears to be, at least has been described to be a computer printout. Can you tell me first who generates these reports?

A. These are produced in biochemistry by our clerical staff.

document is entitled "A Clinical Chemistry Cumulative

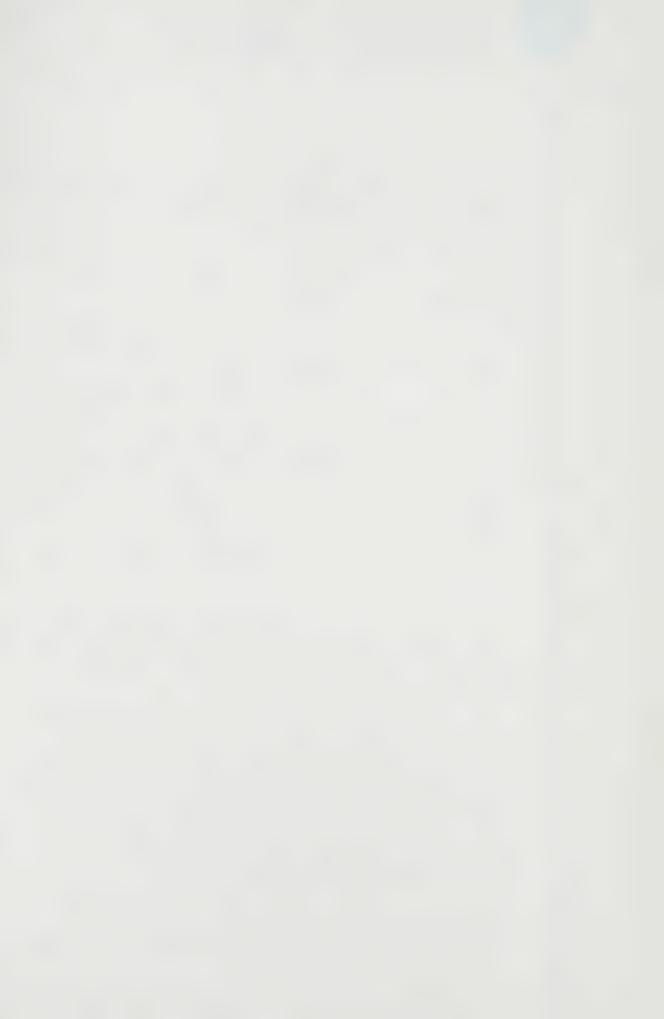
Q. All right. And when you say they are produced in biochemistry, does that mean that the actual document with all of the information contained in it is physically printed and distributed from the biochemistry laboratory?

A. I think that currently that is the case, yes.

 $\Omega$ . All right. Talking in the time period, July, 1980 through March of 1981, was that the case then?

A. These are all produced from a central computer which has various printers on it. I cannot tell you specifically whether at that particular time the computer printout was produced by a computer in the Computing Department or a printer in the Biochemistry Department.

Q. All right. Wherever the form itself was produced, Doctor, would I be correct



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in assuming that the information that is recorded on the document came from the biochemistry lab?

- A. That is correct.
- Q. All right. And was it part of the responsibilities of the administrative staff in the biochemistry lab to take the results of any particular assay from the digoxin books where they have been recorded and to program them into or to provide them to the computer data base at the Hospital in order that these forms could then be generated?
  - A. Yes, the clerical staff.
- Doctor, I would like you briefly to explain the meaning of a number of the entries on these forms and, again, not with any particular reference to Kevin Pacsai, but at the top right hand side of the page you will see that there is a timing indication and a date. Can you tell me, Doctor, are we correct in interpreting that to mean the time and the date upon which the form itself was produced?
  - A. Yes.
  - Q. All right.
- A. The piece of paper itself.

  Can I just come back to that statement that I made



in that on occasion technologists themselves go to the computer terminals and put results in but frequently it is the clerical staff who do this.

- Q. Those would be technologists from the biochemistry lab though?
  - A. Yes, that is correct.
- as well across the top of the page a series of categories with particular information set out. It includes the name of a particular patient, what we have been taking to mean the admission number, the history number, an indication of the sex of the child and the birth date of the child and the admission date. Can you tell me first where that information comes from?
- A. This information comes from the central computer for which there are terminals in the admission area.
- Q. I'm sorry, Doctor, perhaps I
  put the question badly. I had understood you to
  say that either the administrative personnel or,
  as you further explained, the technologists from
  the biochemistry lab would be responsible for
  programming the results of any particular assay into
  the computer data base in order that these forms



could be generated. Do I have that correctly?

A. That is correct.

Q. All right. Therefore, would people from the Biochemistry Department as well provide to the computer the information necessary to indicate the admission number for any particular patient, the birth date of any particular patient or the history number for any particular patient, or is that information already stored on the data base?

A. I believe that is already stored on the data base.

Q. All right.

A. There will be some patients in the Hospital who never go to the Biochemistry

Department and yet whose records are being accumulated in the computer and who have received an admission number and who have this information available.

final category of information in that column, reading across the page is an indication of the ward. In this case it happens to be 4B. Can you tell us what significance that entry has?

A. Well, this is the ward to which the patient was admitted and provided that the



patient hasn't moved very recently, that is the ward where the patient is located.

O. All right. That is not then
I take it an indication as to the ward which was
intended to receive the document reporting the
assay result, but rather it is an indication of the
ward to which the patient was last admitted.

A. It is the responsibility of the ward to make sure that the information that we have is updated as quickly as possible afterwards. So, when the child is admitted an addressograph plate, a plastic plate is very often prepared with all this information contained on it from which requisitions, this identification information is transcribed.

Q. All right. My only point was, Doctor, does the information in that column indicate to you and your lab the identify of the ward or the department within the Hospital who is to be informed of the results of the assay?

A. On this particular sheet of paper?

On any printout of this kind, when you look to that column and see an indication of a particular ward, does that mean to you or does



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that identify for you as the biochemist responsible for these assays, the ward that is to be informed of the results of the assay?

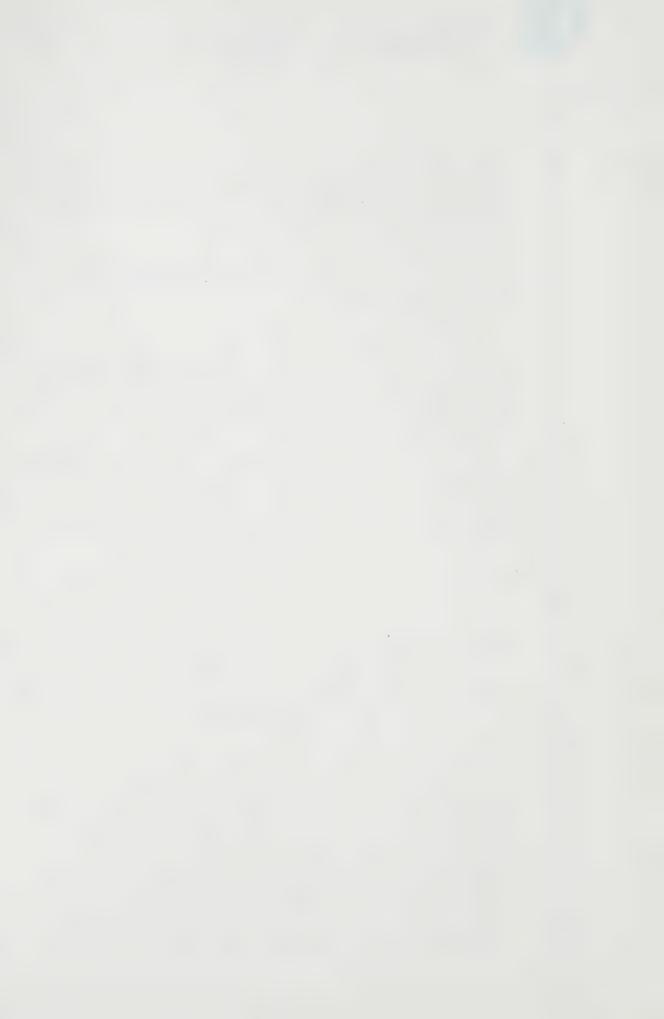
A. This sheet of paper doesn't inform us of that.

Q. All right.

A. This sheet of paper directs the people who takes these reports to the ward to which these reports should be taken.

Q. All right. So, it is intended to identify the ward that is to receive the biochemistry printout, the computer printout?

- A. That is correct, yes.
- Q. Thank you, Doctor.
- A. You see, these are produced at 0339 hours, this particular one, for example. So, the majority of people in biochemistry are, you know...
  - Q. Not there?
  - A. No.
- as is obvious we can see from the left, the column on the left hand side of the page a number of categories for information. Once again we see an entry for date. We have been interpreting that information to be the date upon which the sample



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was taken. Is that correct?

- A. Yes.
- Q. Similarly the hour of collection.

  Again, we have been interpreting that to mean the hour or the time the hour at which the sample was actually collected.

A. The hour indicated to us on the sample requisition that we received.

Q. All right, and indicating the hour at which the sample was taken.

A. Yes.

Q. All righy. Similarly, the next column is specimen type, and we see minor variations here from the information that is set out in the digoxin books, but reading across where we see the letters ART, do we correctly take it that that refers to a sample from an artery?

A. Yes.

Q. And where we see VEN, it is a sample from a vein?

A. Correct.

Q. All right. And when we see O, does it have the same meaning as it does in your digoxin book that you have described?

A. Yes.



	Q.	All right.	Then similarly,	
Doctor,	the next o	column of information	ation appears to	
be volum	e weight a	and then millili	tres per gram. Ca	àr
you help	us as to	what information	n was intended to	
be set o	ut there?			

A. Yes. If any of these samples had been a urine sample then a 24 hour collection or another collection of known volume, the volume would be stated in this particular case and in this particular line.

Q. Does it apply at all to digoxin?

A. No.

Q. All right. The next column, Doctor, Duration, Day, Hour, can you tell us what is intended to be set out there?

A. That again is for generally a urine collection or possibly a stool collection; the duration of that collection. So, for example, there might be 2,400 mls in one column and just beneath that it may say 24 hours.

- Q. All right.
- A. So, it would --
- Q. I'm sorry?
- A. I'm sorry, yes.



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- Q. All right. Once again, Doctor, I take it it has no application to digoxin?
  - A. No.
- Q. All right. And then we come to the specimen numbers and we have been reading that information as simply being the specimen number that was ascribed to any particular sample and that you have told us is originally drawn from the requisition form that happens to be filled out?
  - A. That is correct.
- Q. All right. And those numbers should correspond to the sample numbers indicated in your digoxin books for any particular sample?
  - A. Yes.
- Q. All right. And then, Doctor, we see the results of various assays set out, the category of which type of assay was conducted and then the results beside it. Can you tell me, in any given case, Doctor, for example, if you look at the sample that was taken on March 11th, 1981 at 4:15 in the afternoon do you see that?
  - A. Yes.
  - Q. From an artery?
  - A. Yes.
  - Q. That is Sample No. J05428.



A. That's correct.

Q. If we read down in that column, Doctor, does it mean that all of the assays which are shown to have been conducted and all of the results that are reported were taken and made in respect of that particular sample?

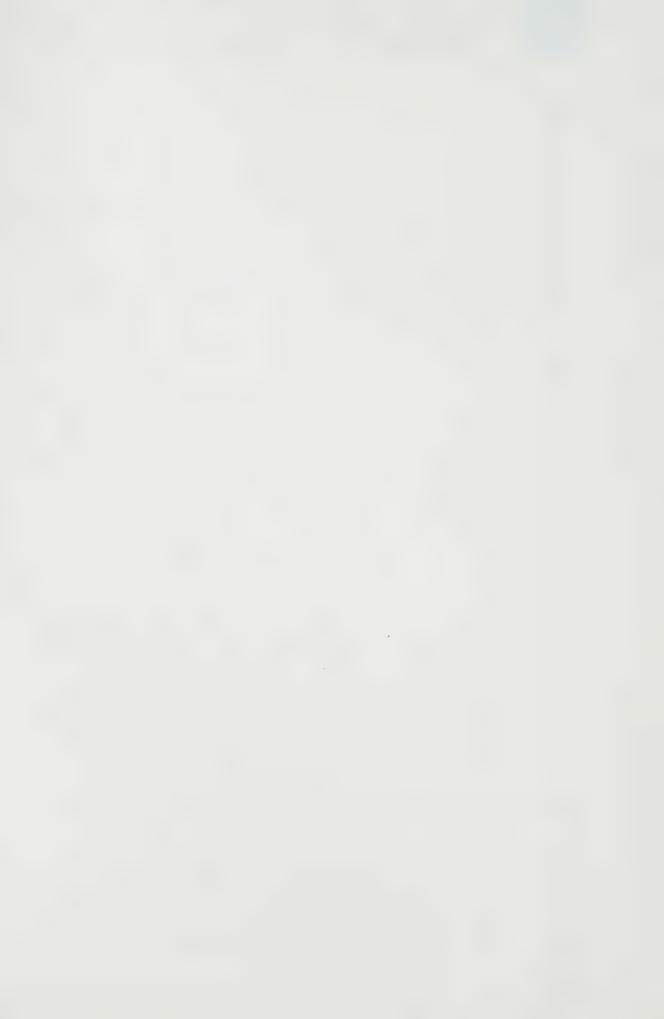
A. Yes.

Q. All right. Then, Doctor, we see in a number of cases again the letters NSQ.

I take it that has the same meaning as it does in your digoxin books, not sufficient quantity for sampling?

A. That's correct.

Q. All right. In some situations, Doctor, we see a footnote. I draw your attention for example to the digoxin level which is reported under the column March 12th, 1981 and we see an asterisk and then the sign for greater than 10 and then underneath that a footnote, it says "See E". If we look to E below it shows that there was an insufficient quantity of the sample for further dilution. Can you help me, Doctor, when we see footnotes on those forms, do those footnotes refer to the sample result that is recorded immediately above the footnote, as appears to be the case with



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this one?

is the case.

- A. Yes, I believe in general that
- Q. All right.
- A. Unless there is an overriding comment which will apply to all tests in that particular sample.
- Q. All right. And we see as well, Doctor, in this particular case an asterisk and, as I said, a greater than 10 nanograms indication?
  - A. Yes.
- Q. And at the bottom of the page in the left hand side we see results flagged, and asterisks were reported today. Can you tell me, Doctor, what the significance is in any case where an asterisk appears beside a particular level?
- A. It means that this particular sheet of paper, this particular report is the first one after which that particular result has been reported.





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I understand that, Doctor. 0.

Are you saying then when an asterisk appears it means it is the first time that that result has been reported in writing on a clinical chemistry form?

It is the first time Α. according to the computer that it has produced a report. A printed report on that particular result.

Right. What then, Doctor, do the words at the bottom on the left mean when it says "Results flagged with an asterisk were reported today"?

It means that on the 14th of March generally speaking the first print-out of the results of the 12th of March, that particular sample, was being reported today.

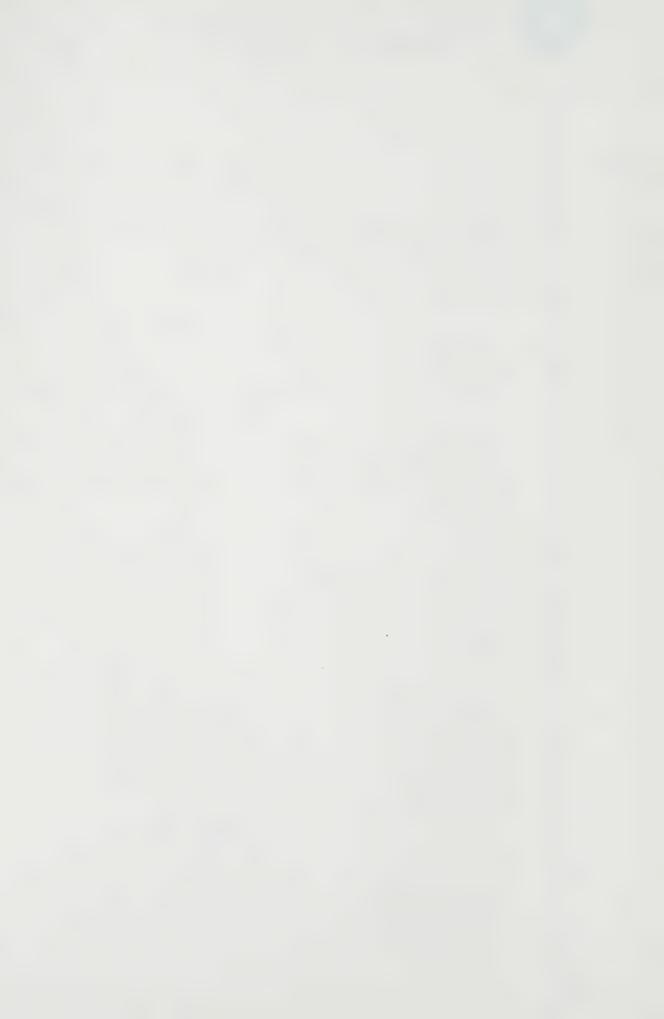
Does that mean then, Doctor, 0. that is essentially an indication from the computer that the very first time that that level of greater than 10 was being reported in one of these reports was on this report dated March 14th?

In general, yes.

The object of this is to indicate to the person looking at this report, to draw their attention to particular items of new information.

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The result of	the pH on the 11th	of March has been
reported on a	computer print-out	previously, and
that is		

Q. And that is why there is no

asterisk?

A. And that is why there is no asterisk, yes.

THE COMMISSIONER: I am sorry, where is that? The pH was 7.31?

MS. CRONK: Yes.

asterisk with that individual result simply because as far as the computer is concerned it has produced a report previously which contained that information.

MS. CRONK: Q. I take it then,

Doctor, that the indication ---

THE COMMISSIONER: Sorry, Miss Cronk,

I just don't understand this at all because surely...

MS. CRONK: Perhaps I can assist, Mr.

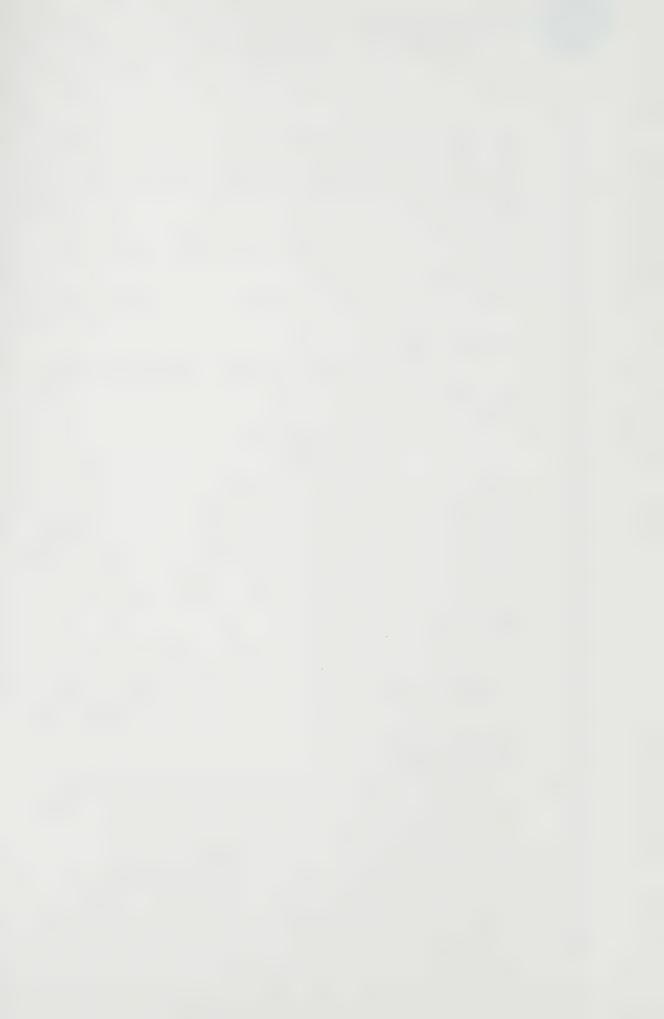
Commissioner?

THE COMMISSIONER: Yes. All right.

MS. CRONK: Q. These reports, Doctor,

are cumulative, are they not?

- A. These are cumulative, yes.
- Q. And I take it on a given day



shown?

once the information is available in the computer the results that have been fed into the computer will be printed out on one of these forms?

A. Yes.

Q. And the computer will as well provide any other levels in the same category, for example, digoxin, if there was a level freshly fed into the computer, if I can put it that way?

A. Yes.

Q. In time for it to show up on the March 14th print-out; it might as well show a digoxin level for March 11 if the computer knew about that one?

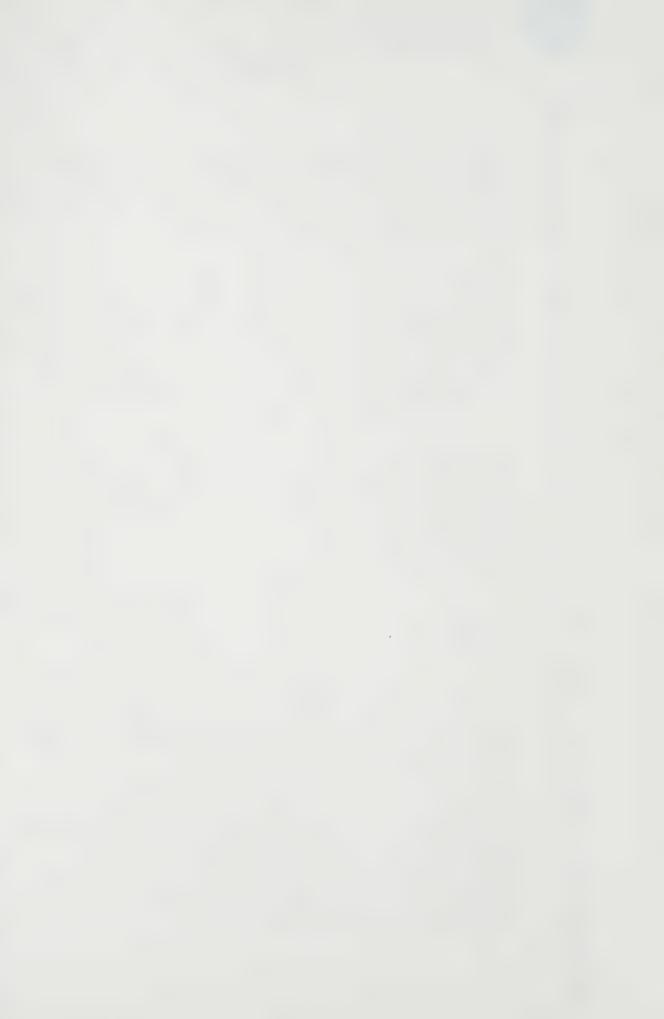
A. Yes.

Q. All right. The two would be

A. Yes.

THE COMMISSIONER: You see if we turn back a page and see that on page 82 we will see that those figures were all reported.

THE WITNESS: Yes. This page is the first written report of all these results. The first opportunity that the computer had to report the results of the 11th, that were taken on the 11th of March, was the following day.



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MS. CRONK: Q. And that is indicated by the computer for computer purposes by the affixing of an asterisk?

A. Yes.

Q. So where we see one on page 82 beside each of those results it means the very first time the computer has produced a written report showing those results?

A. Yes. A printed report.

Q. Now hypothetically, Doctor, but still with page 82, (that print-out was dated March 12th) if the very next day March 13th the computer was asked to print out another report ---

A. Yes.

Q. Right? And because the results are cumulative, those results would show up again I take it?

A. Yes.

THE COMMISSIONER: But without an asterisk?

MS. CRONK: Q. They would be without an asterisk because they had been reported previously?

A. Yes.

THE COMMISSIONER: And if we look at page 81 that is exactly what we find.



THE WITNESS: Yes.

MS. CRONK: Q. Do I have that correctly, Doctor?

A. They would be produced on the next occasion without the asterisk.

Q. I take it then, Doctor, when these reports indicate with an asterisk and with a footnote at the bottom, "Results flagged with an asterisk were reported today", that does not refer in any way to whatever oral reporting of the result may have taken place?

- A. That is correct.
- Q. All right. Thank you, Doctor.
- A. Can I just say in addition
  that many of these patients have lots and lots and
  lots of results, and the object of the cumulative
  report is to produce on one or two sheets of paper,
  the minimum of paper, all the results that the doctor
  may wish to have recourse to.

What this means that if you receive a cumulative report today you should really throw away the cumulative report that you got yesterday because that information ---

- O. Is now ---
- A. is now repeated and is



outdated.

Q. Yes.

A. And the page numbers will change. In fact it is brand new information coming along and it has not been able to get on to one page, then the page number at the top will be updated to page 2 which means that page 1 is full.

O. I see.

A. So that the case record right at the end of everything should have all the information in there, but it shouldn't really have the information that has been produced already that is on a dated print-out.

Q. The object is to simply keep full information in respect of all levels that were recorded but to keep it in as compact an amount of paper and recording forms as is possible?

A. That is correct. That is why I am a little surprised to see page 1 here, an old version of page 1 which has been updated subsequently. That in theory should have been thrown away.

Q. Right. I see. Thrown away, taken off the medical chart entirely?

A. Taken off the medical chart.



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Q. Doctor, as	s I	understand	
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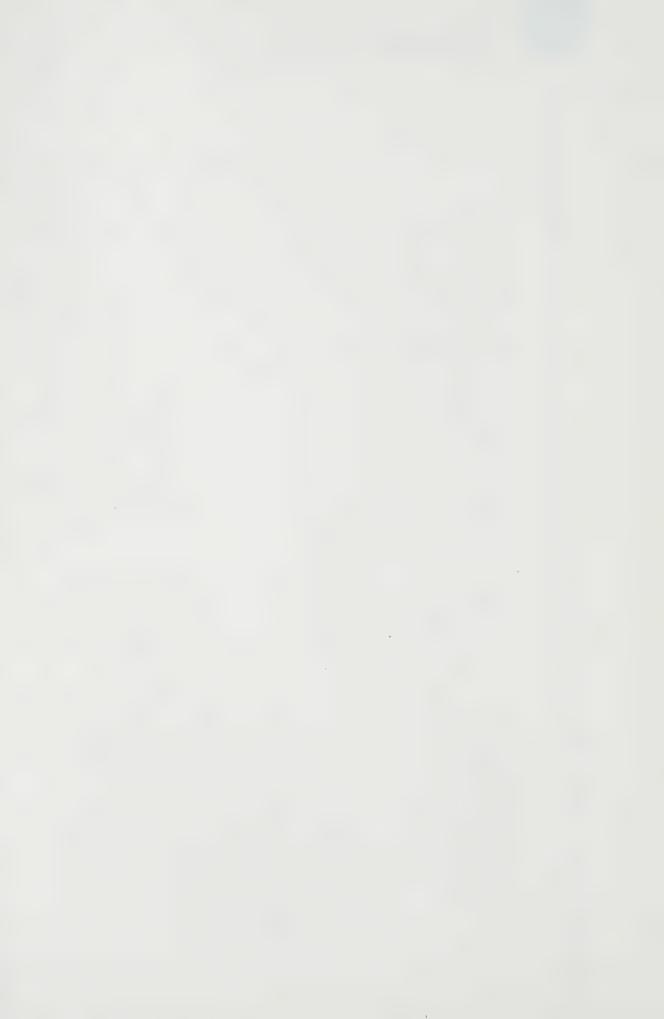
There is only one overriding Α. occasion when an asterisk may appear on the computer sheet, and that may not be the first occasion that a printed report has been produced for that particular result. This is if we need to go into the computer at some stage and adjust a result or add information to that and produce a print-out on that particular occasion. So you cannot say for sure that if something has a date - supposing we had to produce a page with additional information on (I was thinking very much after this date) then - sorry, I take that back. I am getting lost.

All right. . Well, Doctor, 0. perhaps if your thoughts clarify on that you can bring it to our attention later on this morning.

> Okay. A.

Dealing with the reporting of any particular digoxin assay result, as I understood your evidence when you previously testified you told us that the results of any particular assay were reported orally to the ward or to the department within the Hospital that had originally requested the assay. Do I have that correctly?

> A. Reported?





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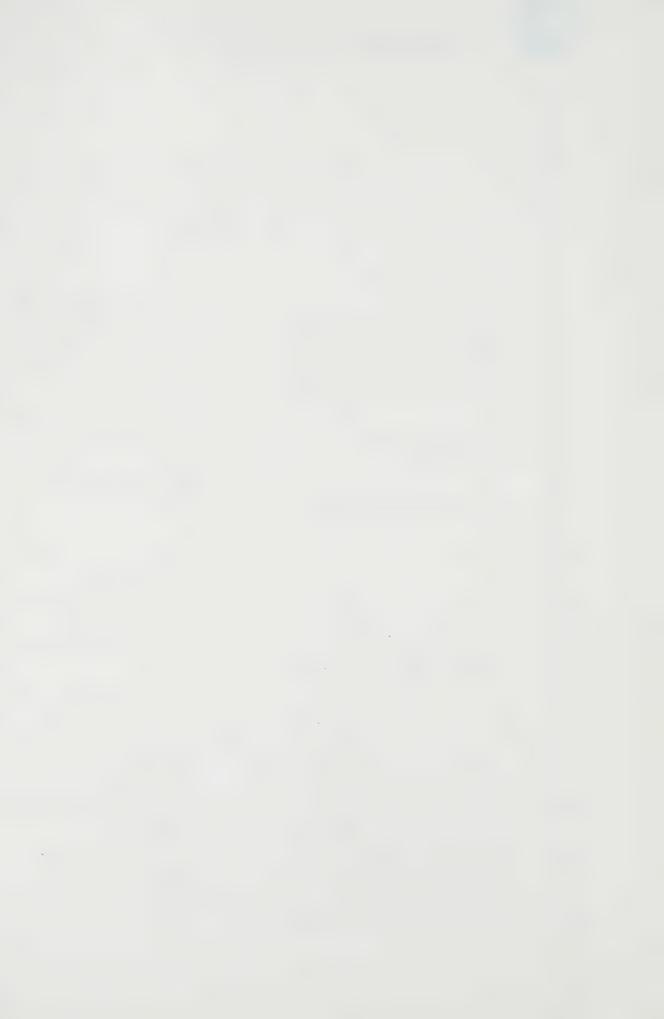
	Q.	Orally that very day.
	Α.	By telephone, yes.
	Q.	By telephone?
	Α.	Yes.
	Q.	And whose responsibility was
it, Doctor, int	ternal to	your laboratory to see that
those results v	were repo	orted by telephone on the day
that the assay	was run	and was complete?
	A.	This was the technologist's
responsibility	to do th	nat.
	Q.	And was that a matter of
uniform and req	gular pra	actice
	Α.	Yes.
	Q.	- in your laboratory?
	A.	Yes, it was.
	Q.	And that was the case in the

Α. Yes.

period from July 1980 to March 1981?

0. All right.

A. When you indicate that was the policy in relation to wards which was the originator of most of our requests, simply so that that information was available for the appropriate treatment of the patient on the next occasion when digoxin perhaps should have been given. Okay? In other words



## ANGUS. STONEHOUSE & CO. LTD. Ellis, dr.ex (Cronk)

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it was for therapeutic reasons.

Q. I can understand why, what the reasons might be for requiring those results to be reported by telephone.

A. Yes.

Q. And you have just addressed some of those issues. But I take it in respect of the duty or responsibility to report them by telephone, as you understood it that was the normal routine in the lab and that happened on a daily basis with respect to any assay results?

A. Yes.

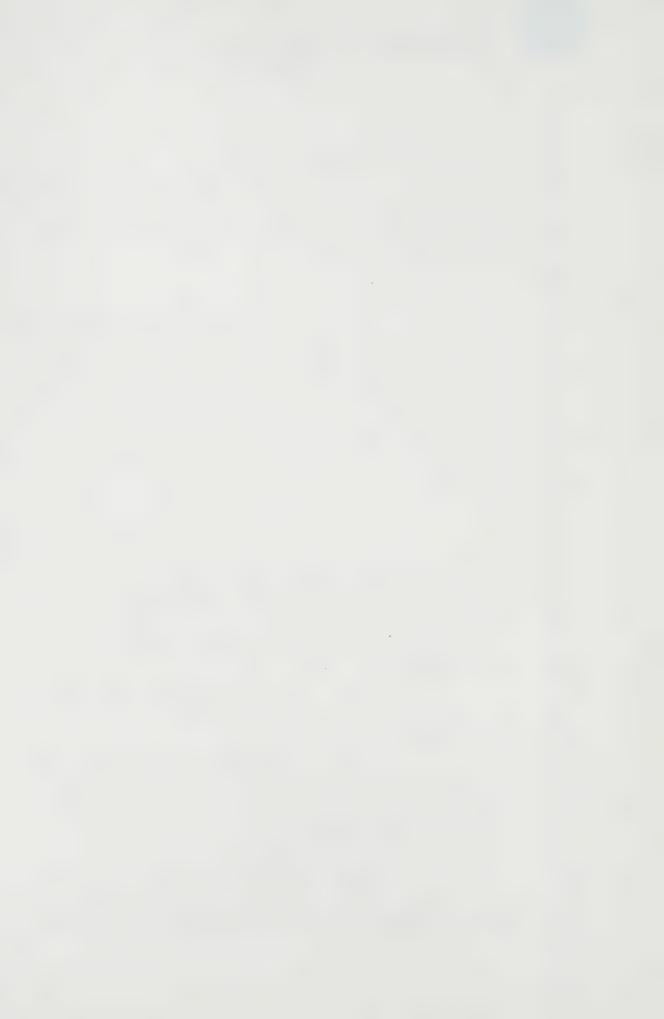
Q. Were all assay results reported by telephone on a daily basis, Doctor, or only those, to use your language a few moments ago, which suggested some abnormality, some irregularity in the reading?

A. No, all results were reported by telephone.

Q. All right. And if they were not reported by telephone on a daily basis would you consider that unusual?

A. Yes.

Q. Doctor, in terms of the written print-out which also contains the results



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TORONTO, ONTARIO

of the digoxin assay, in your experience how long after completion of the assay would these forms be generated, would the first form be generated disclosing that result?

- A. How long after the assay?
- O. Yes.
- A. Usually on the next day.
- Q. All right.
- A. The next available print-out, yes, which is usually the next day.
- Q. I took it from what you said earlier that it was not actually the responsibility of your department to generate the printed version of these print-outs, and then to see in fact that they were distributed. It was not part of biochemistry's responsibility?
- A. Well, this was part of biochemistry's but not part of my section or my technologist's responsibility.
- Q. All right. Did you or did
  any technicians who work under your supervision
  during the time period that we are concerned with
  have any involvement at all in seeing that these
  written print-outs, computer print-outs, were
  distributed to the ward or the person who had actually
  requested the assay?





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			A.	No,	not	the	technologists
n	my	section.					

All right. I take it then, 0. Doctor, as far as your involvement and those of your technicians was concerned, after the report had been telephoned to the ward or to the doctor who had ordered the assay, at that stage your involvement was completed in terms of the reporting of the result?

It was then the responsibility A. to take the digoxin work book to the main part of the chemistry laboratory so that the key punch people could enter the results into the computer.

And after that the involvement was complete?

Yes.

Doctor, could you turn again 0. in the Pacsai chart briefly to page 91.

Do you have that, Doctor?

Page 91? Yes. A.

Doctor, we see here another 0. form of clinical chemistry cumulative report, and it appears to be identical to the other format which we observed on page 83 of the record except for the entries across the top. There is an autopsy number



instead of the patient name, and there is something called REG number as opposed to an admission number, and as well if we look to the last column we see the word "dest" which we have taken to mean destination as opposed to the indication of ward.

Can you help us at all, Doctor, as to what the significance or what the purpose of the information in the last category on that page was on these forms?

A. Well, the destination is to the Pathology Department.

Q. Right. And in this particular case it happened to be Pathology because that is the indication, but my question is, perhaps properly put, is the information in that column as you understood it intended to identify the department within the Hospital who was to receive the assay results?

A. Yes.

Q. All right, thank you, Doctor.

Doctor, I would like to turn now to the specific digoxin assays that you either performed or supervised in the Hospital dealing first with blood samples that were received in the laboratory.

May we turn to the case of Janice

Estrella?



We know, Doctor, that a number of blood samples were assayed during the life of Janice Estrella and as well after her death for digoxin.

Were those assays conducted in your laboratory under your supervision?

A. Yes.

Q. Doctor, could you turn, say, to an exhibit that you have, Exhibit 32B, to Tab 46, if you would. The thick one that I believe you have there.

A. Okay.

Q. Tab 46.

A. Yes.

Q. Page 167. Very near to the back of that tab, Doctor. Do you have it, Doctor?

A. Yes.

O. Doctor, you see at the bottom of page 167 under the date January 7th, 1981, an entry with respect to Sample No. %H56908, and on the basis of your evidence earlier this morning I take it we should properly be reading those entries to mean that that sample was taken at 8:30 a.m. on the 7th of January, 1981; that it was accorded Sample No. %H56908 and that the sample came from an artery and that a level was achieved of greater than 5 nanograms.





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Am I reading that correctly?

A. Yes.

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Q. All right. Doctor, in respect of that particular sample as I understand it the sample was then further diluted and re-assayed by virtue of the fact that when it was first assayed on the 7th of January it was done neat without dilution. Do I have that correctly?

A. Yes.

Q. Right. The first time it was run it was neat, and it was simply off the maximum which could be recorded on the RIA methodology without further dilution.

Do I have that correctly?

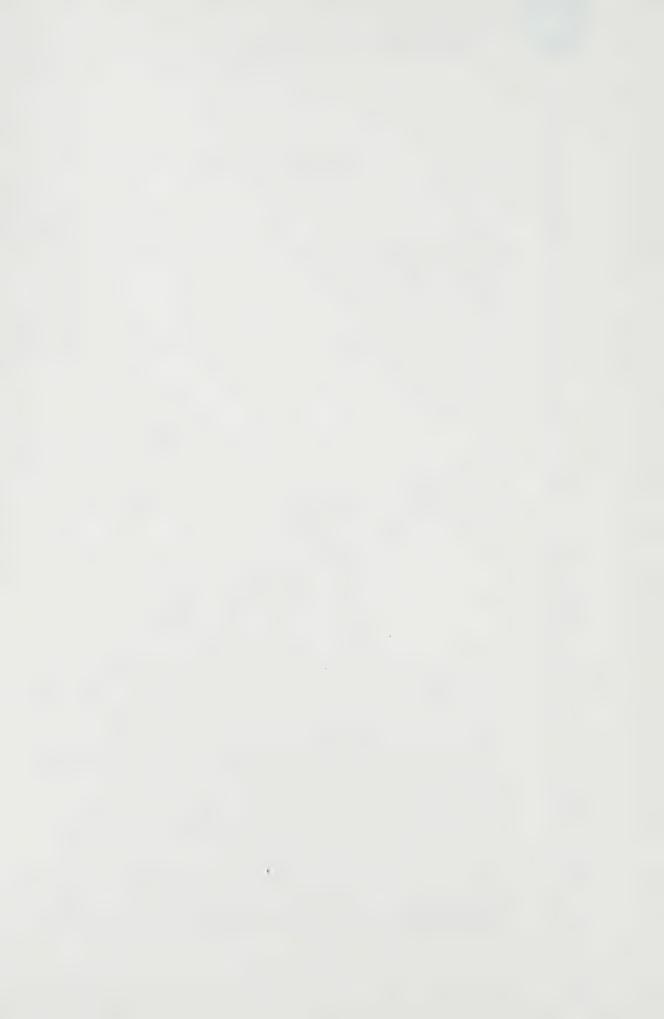
A. Correct, yes.

page 168, the next page, we see the entries for the assays that were conducted on January 8th, 1981, and we see, do we not, that the same sample was diluted and re-assayed on that day with the result this time of greater than 9.4 nanograms.

Am I reading that correctly?

A. Yes.

Q. Doctor, there are a number of handwritten entries beside the name of the patient



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Janice Estrella we have had difficulty reading. Right above the name Janice, can you see them?

- A. Yes.
- Q. Do you know what those entries

refer to?

A. These look like entries by
my technologist to say that one sample - one tube
was analysed at 25 microlitres instead of the usual,
instead of the usual 50. It is not really very clear,
actually, is it?

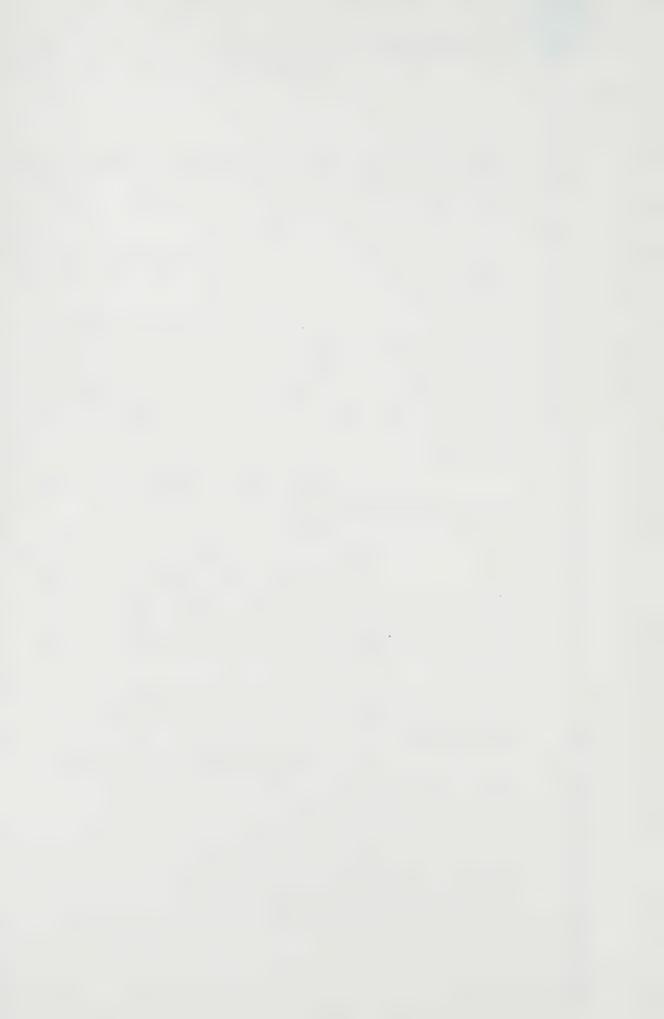
It looks almost as though there were two single 25 microlitres.

Q. For a total of 50 microlitres?

If there were two, Doctor, at 25 the total would be 50 which is the normal amount you told us previously was used for the assay. Is that correct?

A. Yes. 50 microlitres is the usual amount.

- Q. And if there were two here at
- A. Right.
- Q. A combination in total you had the amount that was normally used?
  - A. Yes.



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ean	12	Q.	If that is what the entries	
Car.	i •	Α.	Yes, that is correct, but you	1
re	implying	that :	t went into the same tube. I am	

me saying that this notation indicates that there was relatively little sample left, indicates to me ---

I see.

- there was relatively little sample left, of the order of 50 or 60 microlitres, and that it was necessary for the technologists to use 25 microlitres.

And that would be run in 0. duplicate?

If there is sufficient material A. to do, yes.

Q. And is that what the two entries of 25 would mean?

A. It is a little bit unusual for them to note something twice in that way.

So I take it we can't be sure Q. what that does refer to?

No, we can't. It looks almost as though they were going to do 25 microlitres once and then they attempted to get a second amount, and then noted that second amount.





Q.	All right
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A. But I can't be sure.

Q. And, Doctor, if we look again at the result that is reported, the greater than 9.4, we see again a handwritten entry above it which I have been reading to be diluted times two.

A. Yes.

Q. Greater than 4.7. Am I reading that correctly?

A. Yes.

Q. And, Doctor, we know that the first time it was assayed the result was reported as greater than 5. We saw that on the previous page.

A. Yes.

Q. And now we see that when the sample is diluted times two we are getting a result of 9.4 and the technician has indicated that the mathematical way of computing the result of the dilution is to multiply a greater than 4.7 level times two.

Do I have that correctly?

A. Yes.

Q. All right. Are we then correctly to take it, Doctor, that the greater than 5 level reported the previous day or recorded in



the book the previous day, is in fact the same as if it had been reported at greater than 4.7? The two are synonomous in this sense that they both mean that when the sample was assayed at that time it was over the maximum which could be detected on the RIA methodology and had to be diluted further in order to get a result?

A. Yes.

Q. So in that sense the greater than 4.7 could just as easily have been described as it was in this case as greater than 5?

A. Yes. There was a changeover period when we decided that the best value we could assign to our highest standard was not 5 as claimed by the manufacturers but a value of 4.8 or 4.7.

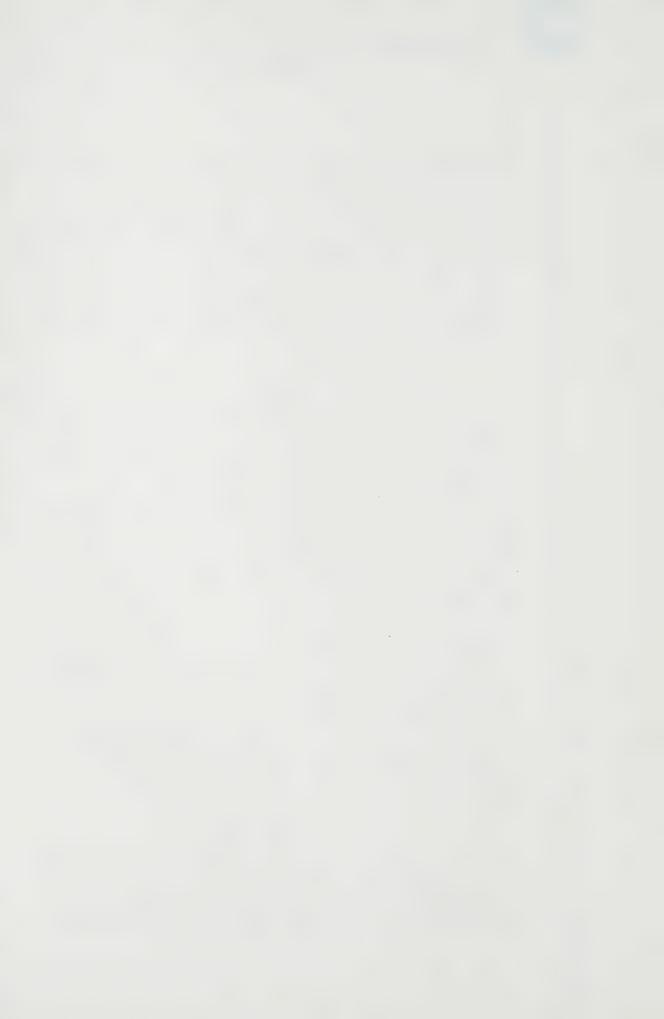
4.7 around this time.

Q. Had that changeover taken place by January 8th, 1981?

A. Without reading through this book and seeing what we had been reporting I can't tell you.

Q. All right.

A. But it looks as though there is a little bit of confusion in my staff's mind as to whether they should be reporting greater than 5



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or greater than 4.7.

Q. Do I take it then, Doctor, that in terms of how your report the first assay result if it is off the maximum, if greater than 4.7 is to be regarded in that context as the same as greater than 5, that this result on the 8th of January of greater than 9.4 could just as appropriately be regarded by us as greater than 10?

It simply means that when it was diluted times two and re-assayed the result once again was off the maximum that could be measured by the RIA method and would require further dilution for a fixed reading to be obtained?

- Yes. Α.
- Is that correct? 0.
- It would require further dilution to get a more accurate answer greater than 9.4.
- Right. And in that context 0. the greater than 9.4 could as easily have been described as greater than 10?
- Well, our best estimate of this result was that our top standard was 4.7, and therefore we said that it is greater than 9.4.
  - Well, I have ---0.
  - That was our top standard. Α.



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Ellis, dr.ex.
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There may be nothing that turns 0. on it Doctor, but I want to be clear about it, and I am having some difficulty with it, because the previous day the result was reported at greater than 5.

> Yes. Α.

And on a dilution of 2, if it was off the top of the measurement which the RIA method was capable of providing by virtue of simple multiplication means the results are greater than 10, is that correct?

> A. Yes.

Doctor, from the review that we have conducted of the medical record, it is apparent that the level of greater than 5 that was achieved on January the 7th was reported by a Biochemistry or Clinical Chemistry printout form dated January 14th, 1981, and that appears at page 159 of Janice Estrella's medical records. I should tell you thought that on my review of the medical record it does not appear there is a Clinical Chemistry printout showing the results of a level of greater than 9.4, or a level of greater than 10. Can you help me as to why that would be the case?

Well, I can tell you - I am sorry, which page are we on?



## ANGUS. STONEHOUSE & CO. LTD. Ellis, dr.ex. TORONTO. ONTARIO (Cronk)

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Q. Doctor, I am sorry, you don't even have to look at the tab that is before you. I am suggesting to you that on the first assay of this sample the result was greater than 5?

A. And that result was produced.

Q. In a Clinical Chemistry printout form which is contained in the medical record of Janice Estrella?

A. Yes.

Q. Then the very next day it is diluted and it is re-assayed and we know the result this time is again off the top of the measurement of which the method is capable and it was recorded in the digoxin book as greater than 9.4. I am suggesting to you that based on my review of the medical record that greater than 9.4 or greater than 10 result does not appear to have been reported in the Clinical Chemistry form to the ward?

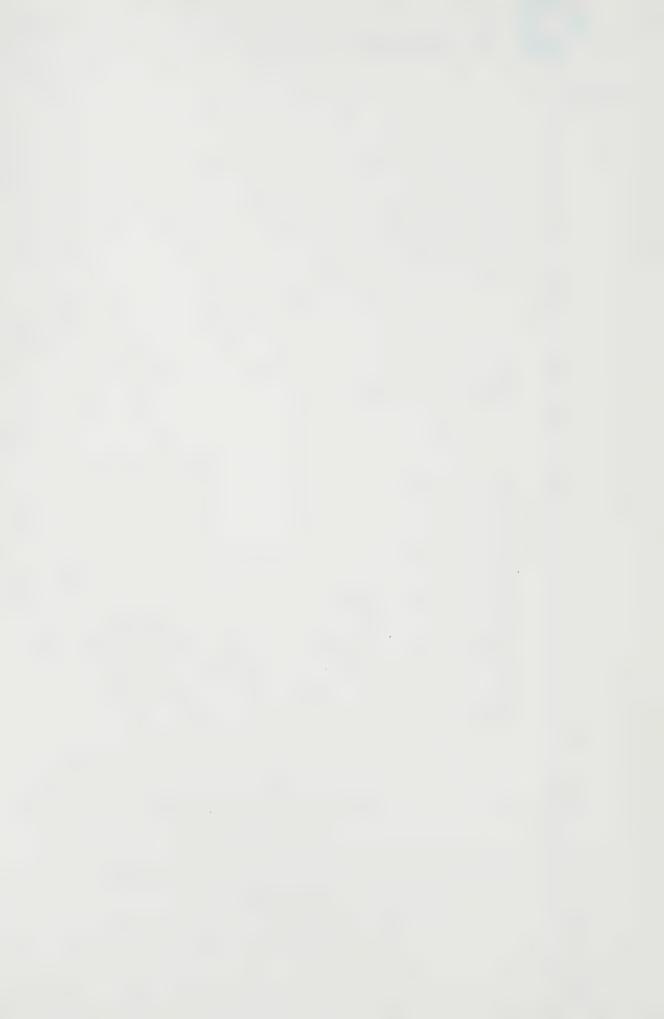
A. Yes.

Q. My question to you is, if that be so, can you help me as to why that would be the case?

A. I can tell you the mechanism by which that failed to be reported to the ward.

Q. All right.

A. Looking at this photocopy on





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page 168 you will see that the registration number, page 568, I am sorry, page 56908, relating to that sample that was greater than 9.4, has been crossed out.

Q. And why is that, Doctor?

A. We would cross out information if we didn't wish the reporting people to attempt to enter that into the computer. In other words, if we knew that it had been reported already and we - not for any reason of cover-up or anything like that; if we didn't wish a report to be produced we would cross through that number.

Q. Why in this - I am sorry, Doctor?

A. That would prevent the person who was trying to enter all these results from going to the computer, entering this patient ID specimen, the specimen identification information and the computer telling her, hey, I have a result before of greater than 5, what do you want me to do? Then they would be faced with a decision as to whether they should really enter it or whether they shouldn't, and then they would have to leave notes for their supervisor for the next day and they would have to come and see us, okay. So that was one reason.

The second reason is, if you look down on Thursday, the 8th, the area that we are looking at



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when this dilution is being done, you will see that we also had a sample dated the 8th, in other words we have a fresh sample. Okay. So in relation to what you do with the digoxin result, or what the doctor does when he gets it back, we had two days' information which makes yesterday's information less relevant than it would have been yesterday. Okay. So yesterday's information as reported by telephone yesterday said, this result is high and the implication is stop the digoxin. On the subsequent day a fresh sample occurs and that is still high, in other words the digoxin value is going down, but it is still above our upper limit. The indications are still stop the digoxin, and there is no difference in reporting greater than 9.4 or greater than 5.

I will come to the second sample in just a moment, Doctor. In terms of the reporting of the result of greater than 9.4, I take it then that the greater than 5 result which was achieved on January the 7th, to the best of your knowledge, was reported by telephone that very day?

> Α. Yes.

Do you know whether the result of greater than 9.4 was reported by telephone on January the 8th?



A. I don't know.

Q. Having regard to the fact that it doesn't appear that there is a Clinical Chemistry printout in written form reporting the result; and having regard to the fact it is crossed out in your book, would you agree with me that it is likely it wasn't reported by telephone that day?

A. It is likely, yes.

The other thing I would say is, as I have indicated before occasionally immunoassays give erroneous results and very rarely, in individual patients for no immediately obvious reason, very, very unusual this is, but on occasion when you take those samples and you dilute them down, then when you do the dilution you get a totally haywire result.

In other words, the specific instance that I am referring to as I have alluded to before is for thyroid stimulating hormones and we have had I think two patients in a period of three or four years where we had reported a result, we had obtained a result of greater than 60 and on dilution of that sample that result of greater than 60 could not be substantiated.

Q. Was there any suggestion in this case, Doctor, that the result of diluting the



Estrella sample times two had the effect of producing an abnormal or unreliable level?

A. No, I think the result that we produced the previous day that said, hey, it is greater than 4.7 or 5, was confirmed by this dilution that it was in fact greater.

Q. High?

A. Yes.

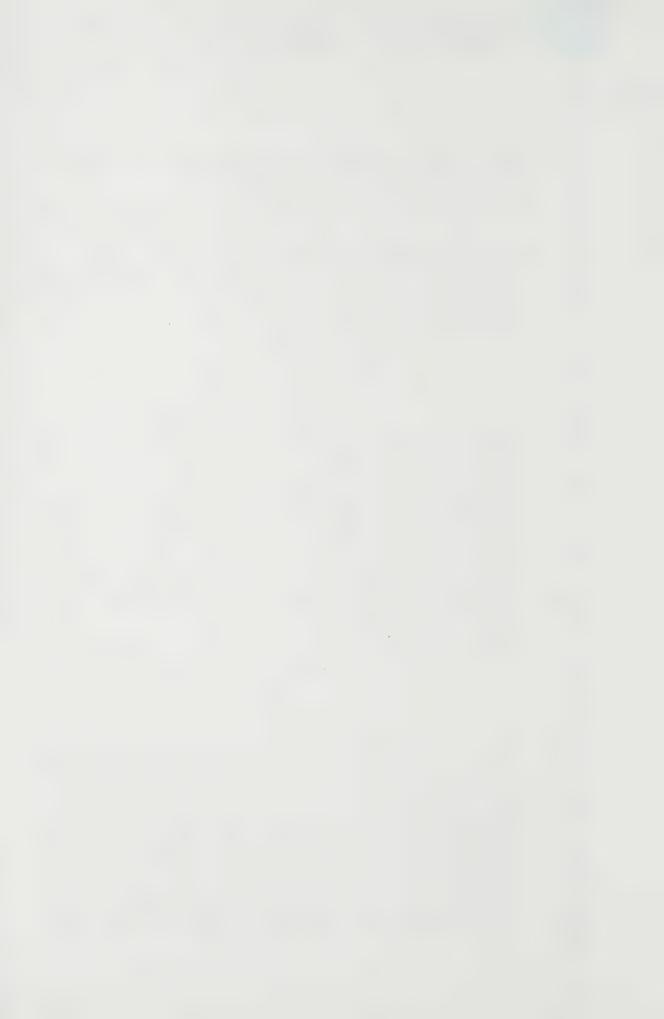
Q. And in terms of the oral reporting of this level, if it be so that it was not in fact reported, I take that to be an exception to the general rule, the norm which applied, and that is every result, not just results that were deemed to be significant, but every result had to be reported by telephone on a daily basis, this would be an exception to that?

A. Yes.

Q. Is that correct?

A. Yes.

Doctor, beside the name Janice
Estrella as well, on that sample there is an asterisk,
and if we look to the bottom right-hand side of the
page the entries of January 12th, there is another
asterisk. As I read it it says: Used new standards
and controls. Can you help me, does that have any



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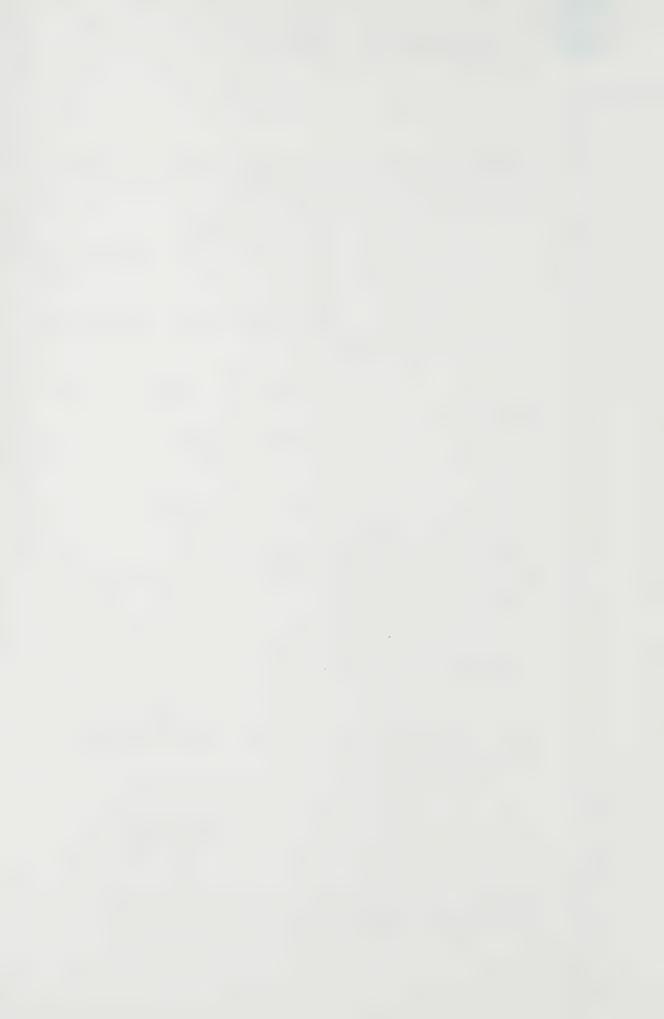
sig	gnificano	e in	n tei	cms	of	the	assay	that	was	conducted
on	January	the	8th	on	thi	s sa	ample?			

- A. No, let me see?
- Q. Do you see where I am referring to?
- A. Yes.
- A. I don't know, I don't know who wrote that.
- Q. Do you know what the reference means?

A. They strongly suggest that somebody was changing standards and controls at around this particular time period and when they exactly wrote that I don't know. It would confirm this view that on one day we were reporting greater than 5 and on another day we were reporting greater than 4.7.

Q. I am sorry, are you saying - well, with reference to the other sample you were reporting greater than 4.7?

- A. Yes. But on the --
- Q. Yes, I understand that.
- A. But on the 7th we reported greater than 5, that if this notation is correct that you have just drawn my attention to, which has an



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asterisk, then that could well be why we reported greater than - 5 was our upper limit on that particular occasion.

Q. My curiosity arose, Doctor, because the asterisk as it happens appears only beside the name Janice Estrella on January the 8th.

A. Yes.

Q. I didn't know whether then to infer that all the assays done on January the 8th were run on new standards and controls, or whether it was merely the sample from Janice Estrella, do you know?

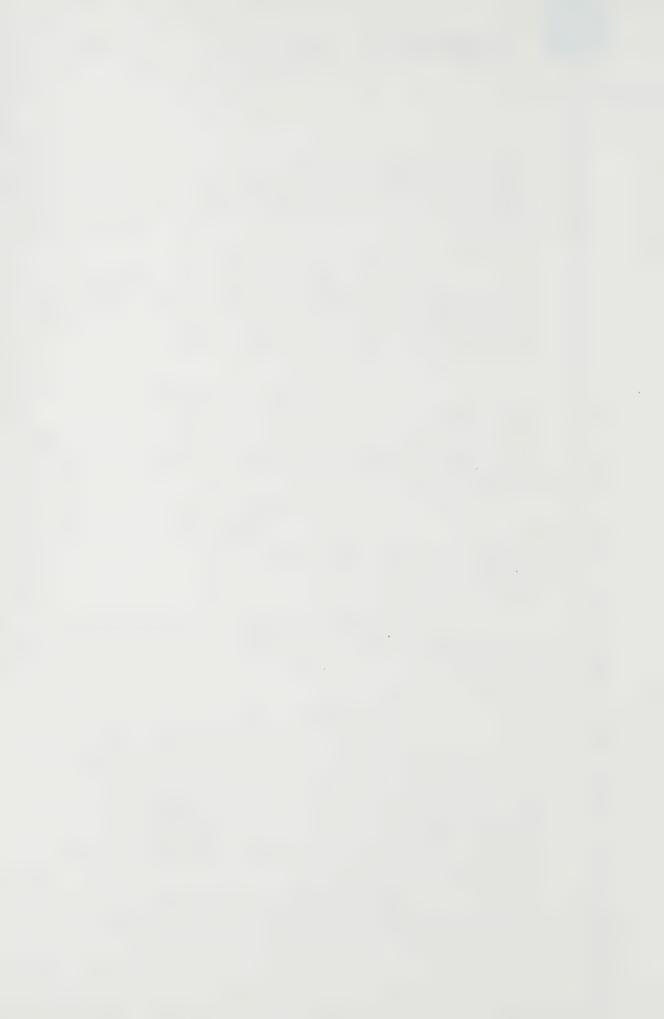
A. I don't know. This looks almost as though somebody was putting it in very much in retrospect, doesn't it?

THE COMMISSIONER: Janice Estrella is the only one who is over the limit of 4.7 or 5 as the case may be?

THE WITNESS: Yes.

MS. CRONK: On two different samples, sir, but the second sample doesn't appear to have been run on January the 8th on new standards and controls, there is another sample reported at greater than 4.7 on January the 8th.

THE COMMISSIONER: That is, the 4.7 is the new standard, isn't it?



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MS. CRONK: I am sorry, we had better clarify that, Mr. Commissioner, and perhaps it is misleading.

Q. I took that reference to the new standards and controls, Doctor, not to refer in any way to the maximum measurement of the scale but rather to refer to the five standards which you have told us when you testified previously were used in the actual run on a radioimmunoassay test to assist in achieving the results. In other words, the standards are known amounts of digoxin that are provided to you by Antibodies Inc.?

A. No.

Q. I am sorry.

A. Standards are vials of standard material provided to us by Corning.

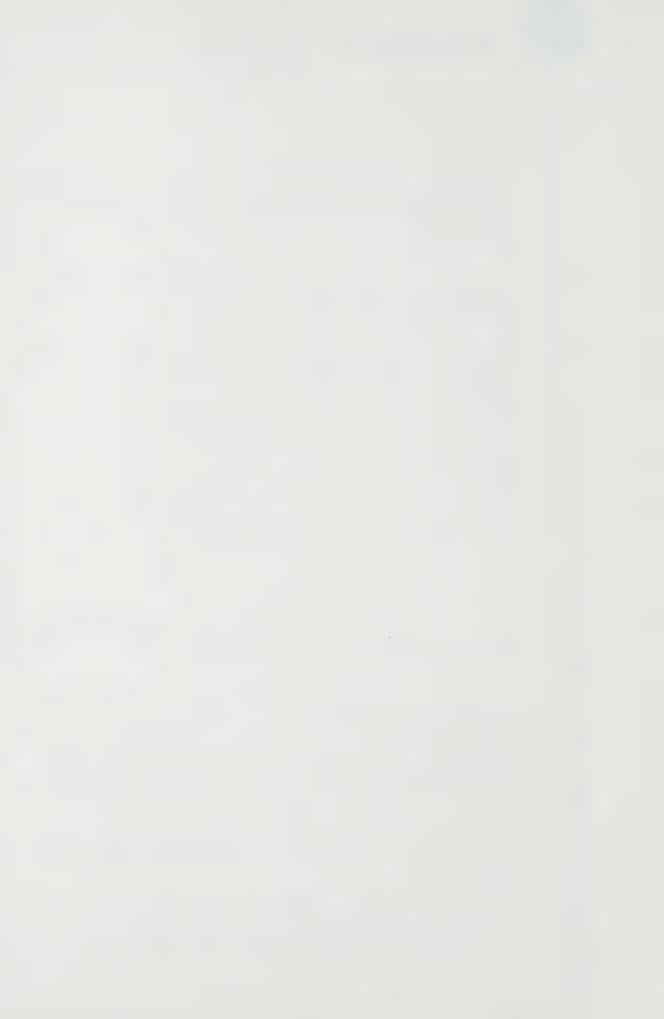
Q. And that is what the reference refers to, it doesn't refer to the maximum measurement of the RIA measure, it refers to the standards that are physically used, the vials of digoxin materials?

A. Yes.

Q. That are physically used in the

test?

A. Right. But they are prepared by additional water to a freeze dried material.





Q. All right.
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A. And that freeze dried material will last for a finite length of time, be it days or weeks.

Q. And when it runs out --

A. When it runs out you have to use new standards.

Q. Right. My only question to you, Doctor, can you help us, and perhaps you can't, as to why, as it appears, new standards were only used on Janice Estrella on January the 8th, and only then on one of two samples that were available from Janice Estrella?

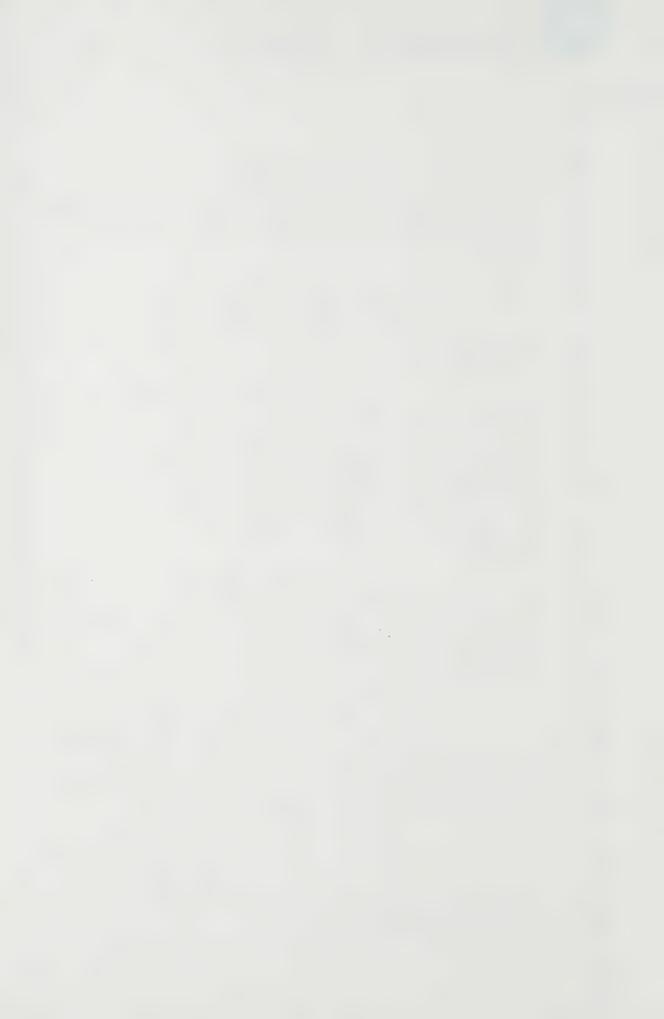
A. No, that would not apply. If new standards were used on January the 8th they would apply to all subsequent samples, not just the individual patient, that is not the indication there.

Q. All right, thank you.

A. It may have been that in retrospect we looked at this page in respect specifically of Estrella looking for something unusual.

O. I see.

A. But on the other hand there is a space at the bottom so it looks as though it was put in after the Monday, doesn't it?





Q. Insofar as you are aware, Doctor, I take it then that that sample was not treated any differently?

A. No.

MR. HUNT: I just have a question and maybe my friend is getting to it. I assume in the book these are separate pages, because they are numbered separately, 168, 169 and the asterisk appears on the bottom of Monday, January the 12th. Has it been clearly indicated that that asterisk at the bottom on Monday, January the 12th, relates back to an asterisk on another page two days before that?

MS. CRONK: Fair enough.

Q. Doctor, can you help Mr. Hunt with that? I must say I assume that to be the case, and Mr. Hunt is quite correct, it is two separate pages.

A. Yes. I agree, I recognize that. Without seeing the original and seeing whether there are any asterisks anywhere else, there don't appear to be. My presumption is that some time after Monday the 12th of January somebody wrote this comment in relation to new standards and controls having been used. Okay. My guess is that there may have been some discussion about whether we should be reporting greater than 5 and greater than 4.7, and perhaps





somebody wrote it in relation to that.

Q. Well, I am sorry, Doctor, I don't want to complicate it any more than perhaps it already has been. I have as it happens the original here for January the 8th, the digoxin book, and the entries for January the 9th appear in part on the same page, and the entries for January the 12th on the next immediately facing page. Do you know, and perhaps you don't, do you know what the significance of that entry is for new standards and controls used?

A. No.

Q. Do you know what the significance is of the asterisk beside Janice Estrella's name on the entries for January the 8th?

A. No.

Q. Thank you.

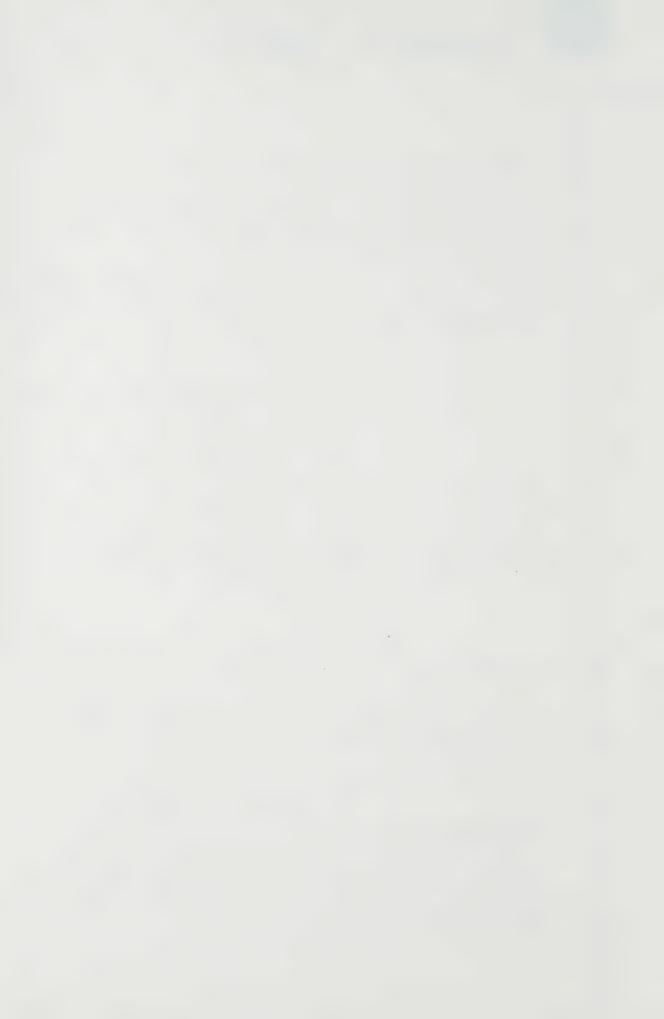
A. The only thing I can say that the ink is the same colour, that ink there, whereas in the photocopy it looks as though this person wrote that asterisk.

- Q. They appear to relate?
- A. Yes.
- Q. Doctor, may we turn then to the next sample which was assayed on January the 8th. You have indicated previously that that was a fresher



sample, it was a sample that was provided to the lab on January the 8th. If we are reading your entries correctly that was a sample drawn at 10 a.m. on January the 8th, Sample No. H56921, drawn from a vein, and it resulted in a level of greater than 4.7, am I reading that correctly?

- A. Yes.
- Once again it came from Ward 4A.
- A. That is correct.
- Q. And that sample as I understand it, Doctor, was again repeated the next day at a dilution of times two, and we see that entry under Friday, January the 9th, and that result at that time was 7.8 nanograms. Do you see that?
  - A. Yes.
- Q. Doctor, that entry as well is crossed out and the word "check" appears beside the level of 7.8 and that is crossed out as well. Can you tell me what significance, if any, there is to the fact that those entries are crossed out?
- A. It suggests to me that the technologist wrote "check" because it was his understanding that this assay was to check on the previous day's assay, not that it was to be reported in the usual way of reporting assays. Okay.



At some stage after this we would report, whatever number we got eventually, we would report that number. Okay. Prior to this point there were, we would quite often report greater than 5 without going any further. That indicated to the floors that they should stop giving digoxin and that was all the information that they needed.

Q. In those circumstances then I take it that the ward might or might not be informed of the fact that you had further assayed a particular sample on dilution and obtained another result?

A. That is correct.

Q. And in this case again the 7.8 level appears to have been crossed out?

A. Yes.

Q. Would you agree with me on the basis of what you have just said that it is unlikely that that result was reported orally that day?

A. Very unlikely, yes.

Q. But it is likely that the greater than 4.7 level was reported on that sample the day previously?

A. Yes, that would have been reported, yes. Sure, in fact there is also a tick by the side of it.



reported?

Q.	The	tick	means	that	it	was

A. That would mean that it went into the computer.

Q. Should there then be, Doctor, a tick beside all of these levels if they were fed into the computer?

A. People are relatively inconsistent.

Q. It can mean that if it is there, but it doesn't mean it wasn't reported if it is not there?

A. That is correct.

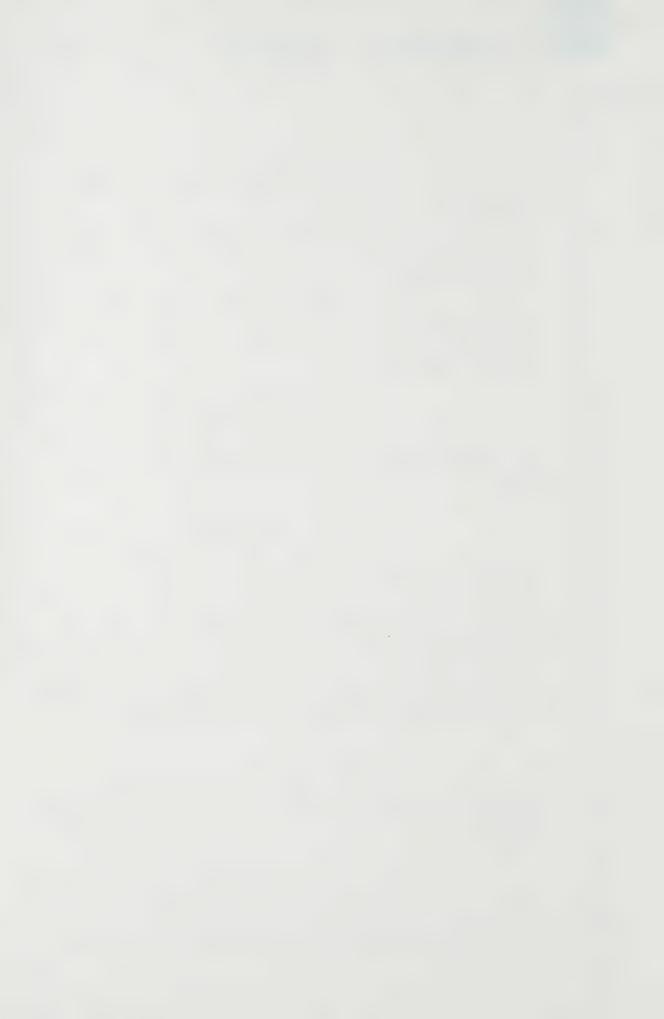
Q. Doctor, can we turn then to the next sample which also appears to have appeared in the Biochemistry laboratory on January the 9th, and that is Sample H57574, and if I am reading those entries correctly that is a sample that was taken at 3:30 p.m. on January the 8th on Ward 4A from an artery?

A. Yes.

Q. And there was insufficient quantity of sample to permit an assay on that particular sample?

A. That is correct.

Q. Doctor, the next sample then the same day, is Sample No. H56924, and that appears





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to have been taken on the ward on January the 9th, 1981 at 9:30 a.m. and this time from a vein; do you see that?

A. Yes.

THE COMMISSIONER: I am sorry, 9:30?

MS. CRONK: At the top of page 169, sir.

THE COMMISSIONER: Oh, yes, I see.

All right.

MS. CRONK: Q. That is taken the next day, Doctor, on January the 9th, and it is assayed on that same day, January the 9th, and it resulted in a level of 4.7?

A. Yes.

THE COMMISSIONER: I wonder if we could, while we are just looking at it, hour of collection. So I can get these hours straight, you have got 9:30 on page 169 of the Preliminary Inquiry exhibit, and you say at 159 of Janice Estrella's Exhibit 91, it seems to be 9 o'clock, did I miss something on that? Where do these hours come from? What are the hours in your book, what do they mean?

THE WITNESS: The hours in the book should be the hours on the sample requisition, yes.

THE COMMISSIONER: Where would they

have gotten this figure of 0900?





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THE WITNESS: On the computer printout?

THE COMMISSIONER: Yes.

THE WITNESS: I can't explain that

discrepancy, they should be the same.

THE COMMISSIONER: They should be the

same?

THE WITNESS: Yes.

MS. CRONK: To assist you, Mr.

Commissioner, I have not seen a requisition form that applies to this particular sample, so I can't assist you as to what time might have been indicated on it as the hour for collection.

THE COMMISSIONER: It might

conceivably be a human error if somebody were to transform from one thing to the computer.

THE WITNESS: Yes.

THE COMMISSIONER: And they put the wrong hour down.

THE WITNESS: It is possible.

Occasionally samples are, not very often, but occasionally labels are stuck on blood tubes or syringes that come in ---

THE COMMISSIONER: At any rate it is either 9 or 9:30. Yes, I am sorry, Miss Cronk.

MS. CRONK: Q. That sample, Doctor,



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January before the child died? A. Yes, on the Friday.

was clearly taken at either 9 or 9:30 on the 9th of

And clearly therefore an antemortem blood sample having been drawn from a vein, would you agree with that? I am sorry, it is clearly an antemortem sample drawn from a vein?

A. Yes, I would presume that. don't know exactly when this child died.

I am sorry, Doctor. The child died on January the 11th, 1981.

> A. Okay, right.

If that be so, it is clearly an antemortem blood sample, do you agree?

> A. Yes.

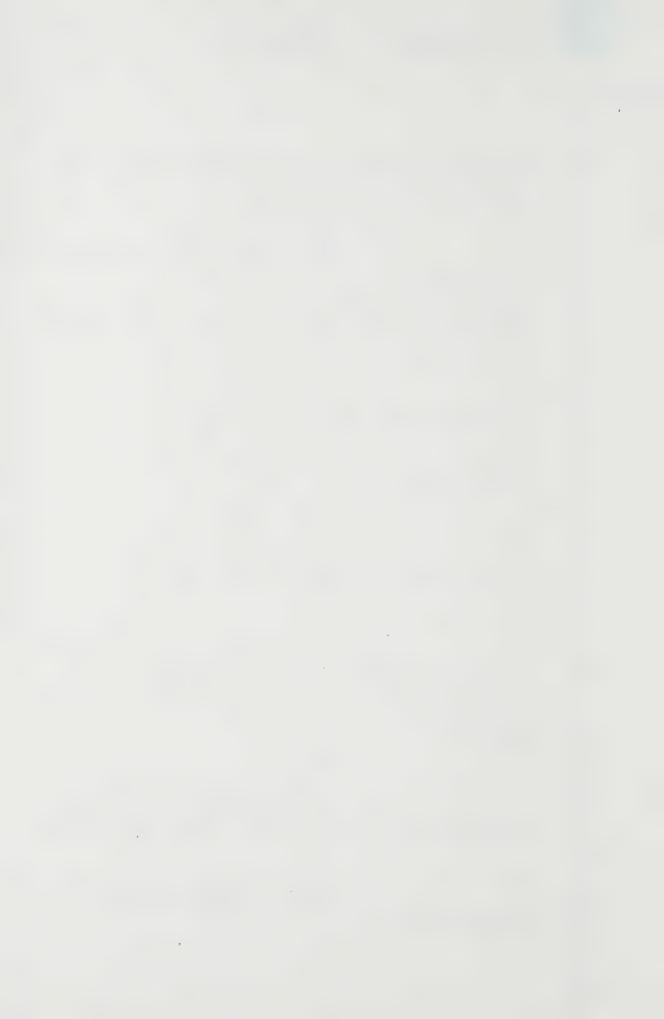
And that sample, Doctor, appears as well to have been diluted and re-assayed on the very same day, do you see that entry immediately below the first?

Yes.

I am having difficulty reading the number, but I take it to be a times two dilution?

> A. Yes.

Q. And the reading this time is expressed to be 5?





A. Yes.

Q. 5 nanograms?

A. Yes.

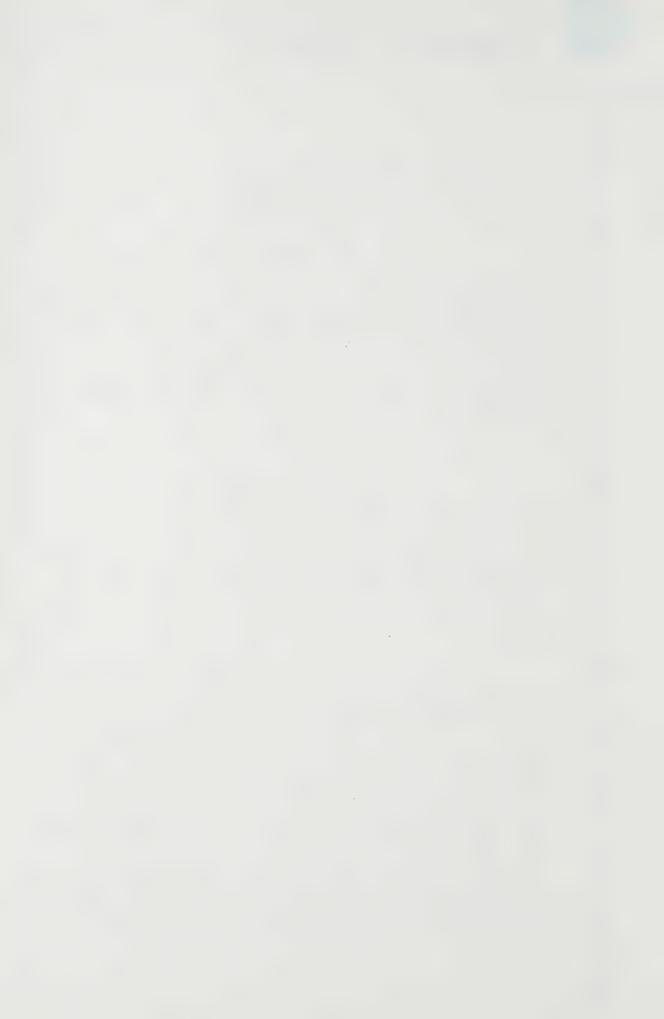
Q. In terms of the significance attached to those two levels in your laboratory, would I be correct in concluding that a level of 4.7 and a level of 5 as they are close to the maximum which the IRA method is capable of measuring would be treated as virtually the same result?

A. Yes.

Q. And once again that particular entry is crossed out, Doctor, and would we correctly then regard that as not the level of 5, as not having been reported by telephone that day to the ward, but rather the level of 4.7 that would have been reported orally?

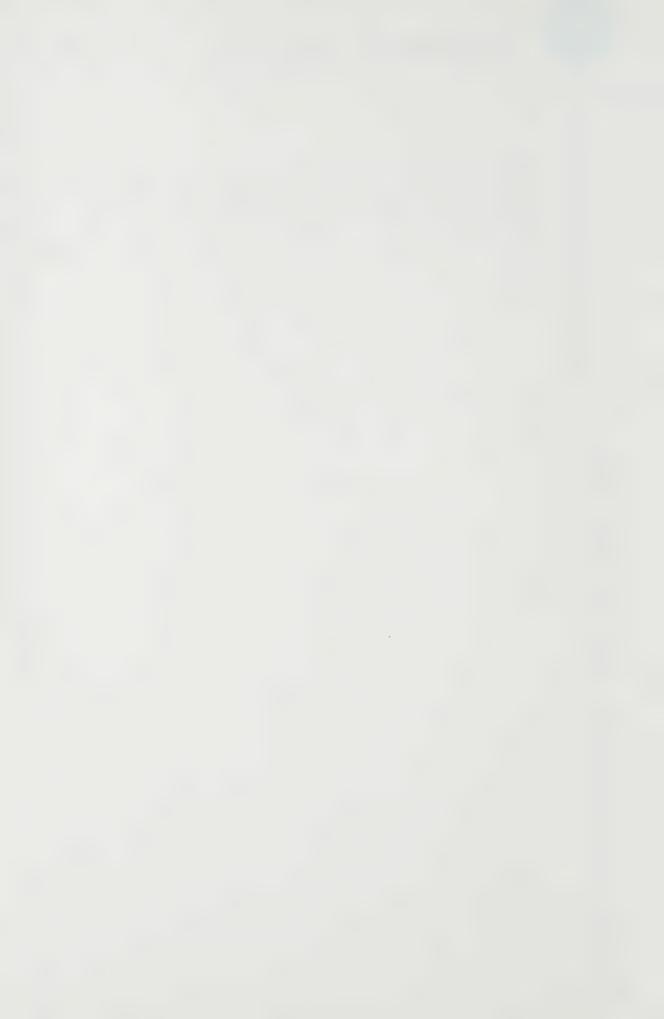
A. Yes, that is correct. Hopefully on the computer printout that result had gone up too.

Q. As it happens, Doctor, with respect to a number of these assays, they were run on January the 8th and on January the 9th as we have seen, yet the earliest printout, the earliest Clinical Chemistry printout that appears in the medical chart of Janice Estrella is dated January the 14th, that is a delay of some five or six days between the day



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that the assays are run and the day that the results appear to be reported. Can you help me as to why that might be the case, reported in writing, or do you know?



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A. I don't know. Was there a flag to indicate that that was the first time that digoxin result was being reported?

Q. I am sorry, in fairness, Doctor, there is not.

A. Okay.

Q. So, do we correctly assume therefore that there had been an earlier printout disclosing that result?

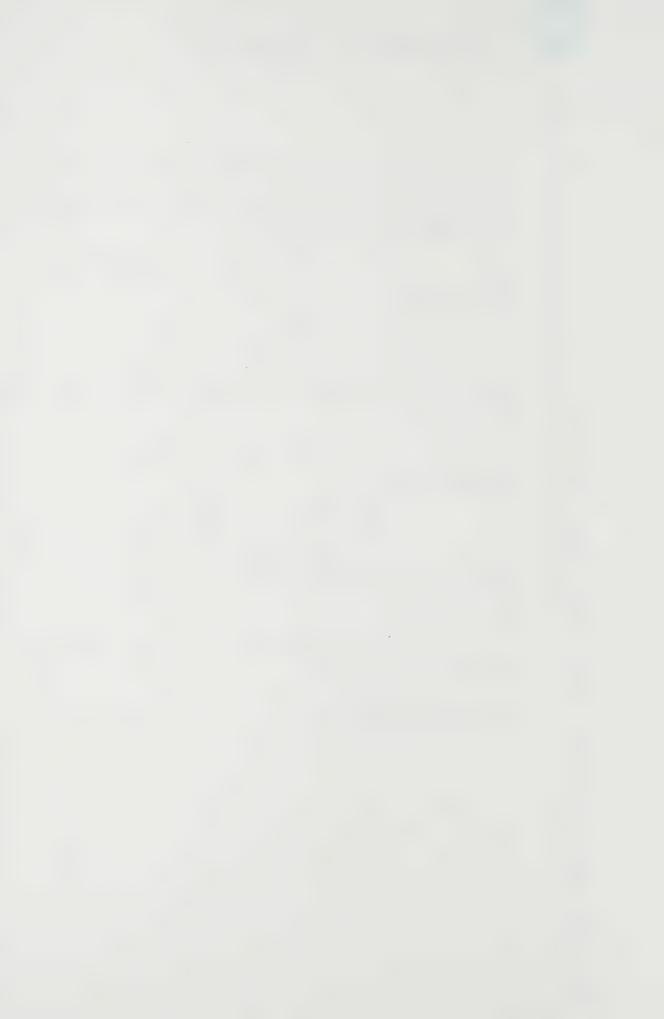
A. Yes, which was updated at some subsequent time.

MS. CRONK: All right, thank you, Doctor.

Mr. Commissioner, I am about to move to the postmortem samples, would this be an appropriate time to break?

THE COMMISSIONER: All right. Then we will rise now until 2:30.

--- Luncheon adjournment.





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--- Upon resuming at 2:30 p.m.

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THE COMMISSIONER: Yes, Ms. Cronk.

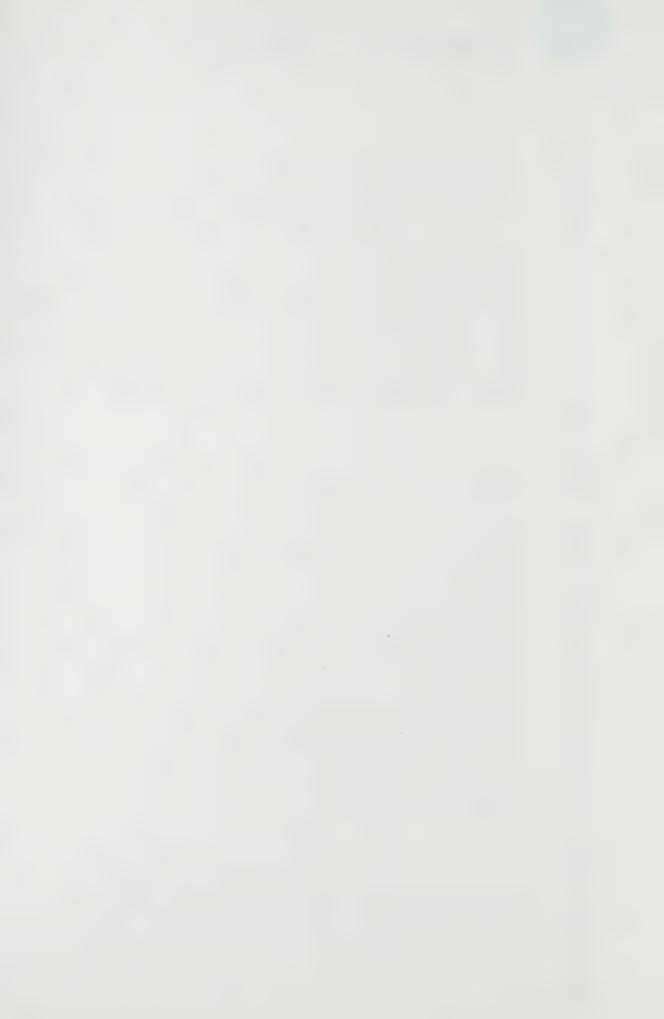
MS. CRONK: Q. Dr. Ellis, just before we broke at lunch we had finished reviewing the antemortem blood samples upon which digoxin asssays were conducted in your lab. I would ask you to turn back again if you would to Exhibit 32B, Tab 46, Doctor, page 169. Do you have that, Doctor?

> Α. Yes.

Q. All right. Doctor, under the entries for January 12th, 1981 on the right hand side of the page, page 169, we see that yet another sample was delivered to the lab for digoxin assay purposes, it is Sample No. G89241. If I am reading your entries correctly the sample came from the Pathology Department, it was taken on the 1st of January at an unknown time on the basis of the entries in your book and on the first assay without dilution it was required that the assay be repeated because no fixed level could be obtained. Am I reading that correctly?

> A. Yes.

All right. Doctor, we see again the initial O beside that particular specimen. I take that to mean that at the time the requisition



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form was provided the technologist in your lab who was checking the requisition form didn't know whether the sample was from a vein, from an artery or what the sample type in fact was and hence the letter O was indicated beside the sample.

A. Yes.

Q. All right. Doctor, we see in handwriting as well beside the name Janice Estrella the words "postmortem possibly diluted specimen". Do you know whose handwriting that is?

A. No.

Q. All right.

THE COMMISSIONER: I'm sorry?

MS. CRONK: Right beside the name, Mr. Commissioner, in small handwriting.

THE COMMISSIONER: 169? Oh, yes, I see it, yes, you are quite right.

MS. CRONK: Q. Doctor, do you know what that reference refers to?

A. The possibly diluted specimen?

 $\Omega$ . Yes.

A. I understand there was some concern about the quality of this particular sample that was received from pathology.

Q. All right. In your experience,



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Doctor, prior to the case of Janice Estrella, had you ever before received a sample from the Pathology Department for the purposes of digoxin assay, to the best of your recollection?

A. It was not our regular occurrence for us to receive samples from pathology.

Q. No, I wouldn't have thought so.

But do you recall receiving one prior to this one

from pathology?

A. No. But I believe that when I went back through the book, when these kind of questions were being asked, I think one had in fact come from pathology a long time before prior to this.

 $\Omega$ . All right. So, this then would have been the second sample of that kind received from the Pathology Department?

A. As best as I can tell, yes.

Q. All right. And that I take it marked this sample as being somewhat unusual in that the source from which it was obtained was the Pathology Department and presumably therefore it was an autopsy sample.

- A. Well, yes.
- Q. All right.
- A. But it also says post mortem.



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	Q.	And what	significance do	
you attach to	that?	Don't the	words post morter	n as
well indicate	that it	is an aut	copsy sample?	

A. Yes.

Q. Doctor, you said that you understood that handwritten reference to mean there was some question as to the quality of the sample.

On what basis did you gain that impression?

A. Yes, I think I was under the impression that the sample requisition contained this information but in fact you showed me this requisition and it doesn't, or at least the copy that you have doesn't.

 $\Omega$ . All right.

A. I cannot remember precisely the exact way in which we happened to come to know it was possibly a diluted specimen but I know that when this sample was being discussed there was always this rider as to whether the sample quality was satisfactory.

Q. When this sample arrived at the lab for testing, Doctor, was the fact that it had been received and the fact that it was a postmortem sample drawn to your attention?

A. During that week I think it did,



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yes. I can't say for sure that on Monday, January 12th that this was drawn to my attention specifically.

- You don't have any recollection one way or the other?
  - Specifically for that day, no.
- Q. All right. Do you have any recollection at all, Doctor, as to when you learned that there was some question as to the quality of this sample?
- If it wasn't on January 12th it was within a few days of that.
- Do you remember who told you 0. or what led you to understand that there was some question about the quality of the sample?
- Α. I think in discussion with my technologist this point arose. I think that at the preliminary hearing flow sheets were prepared, large flow sheets of individual samples and these were admitted in evidence. In referring subsequently to our conversation of last week, to that flow sheet, in fact I think you will find that the flow sheet it says that the tube itself was labelled possibly diluted specimen.
  - $\Omega$ . All right.
  - A. We have reason to believe that



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this sample was not a usual sample.

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Q. All right. Doctor, could you turn to Tab 53. Perhaps you could keep your finger just at that page and turn as well to Tab 53 of the same book. Do you have that?

> Α. Yes.

0. All right. That, Doctor, is a clinical chemistry requisition form bearing the same sample number as this sample number.

> Α. Yes.

G89241. It appears to have been signed by Dr. Glenn Taylor. Were you aware, Doctor, in January of 1981 as to who Dr. Taylor was?

> Α. No.

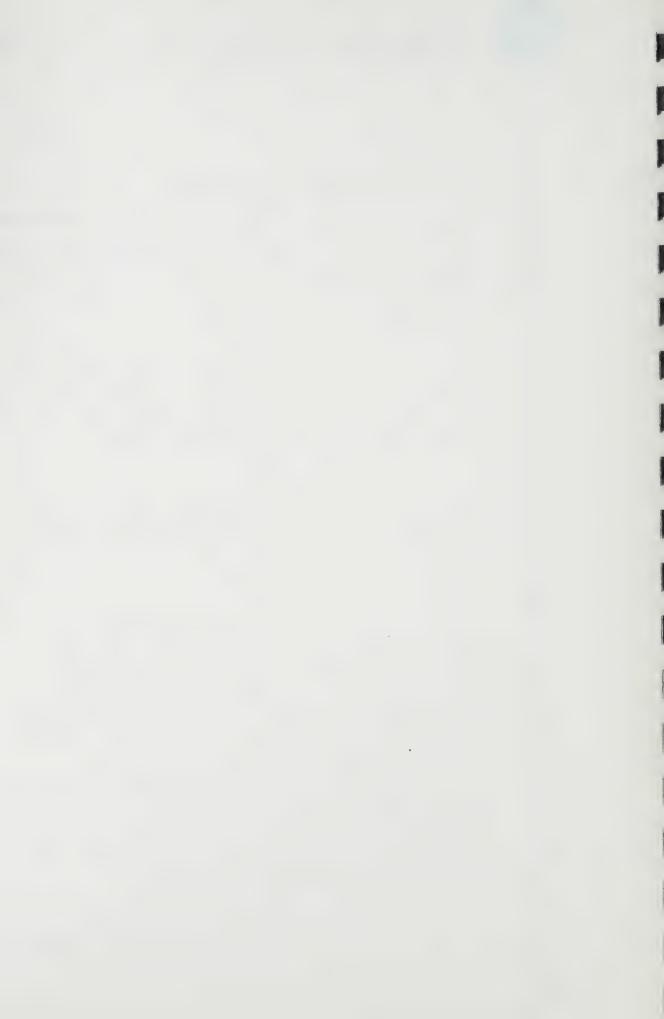
Q. Did you know that he was with the Pathology Department at the Hospital?

Well, having seen this A. requisition that would be the assumption one would make but I didn't know him personally.

And that assumption would be based on the fact that the requisition form indicates that the results were to be forwarded to Dr. Glenn Taylor of the Department of Pathology?

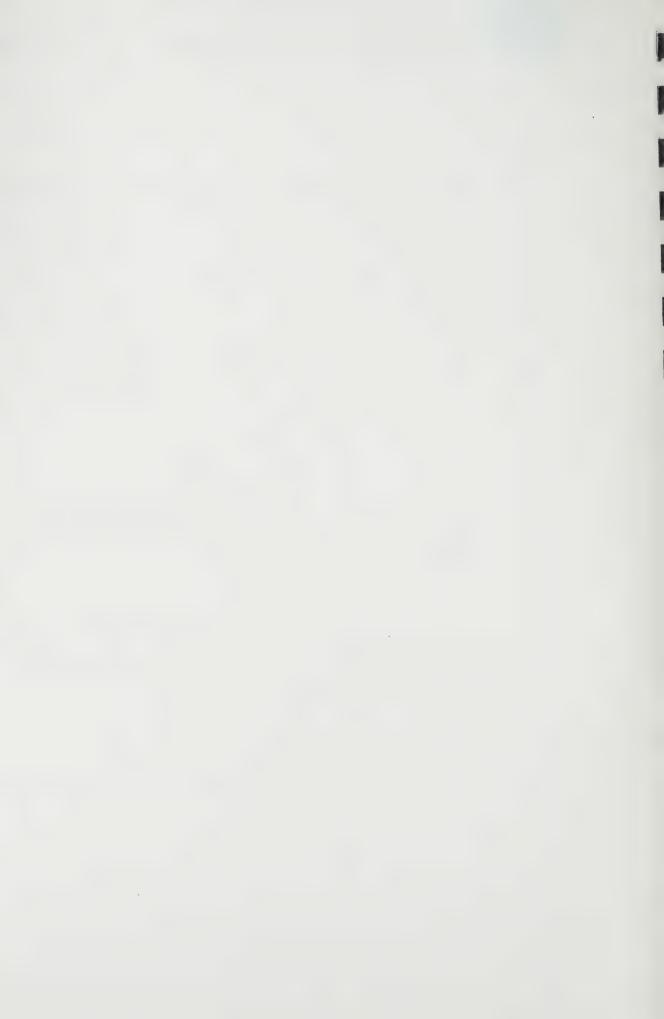
> A. Yes.

Q. All right. We see, Doctor,



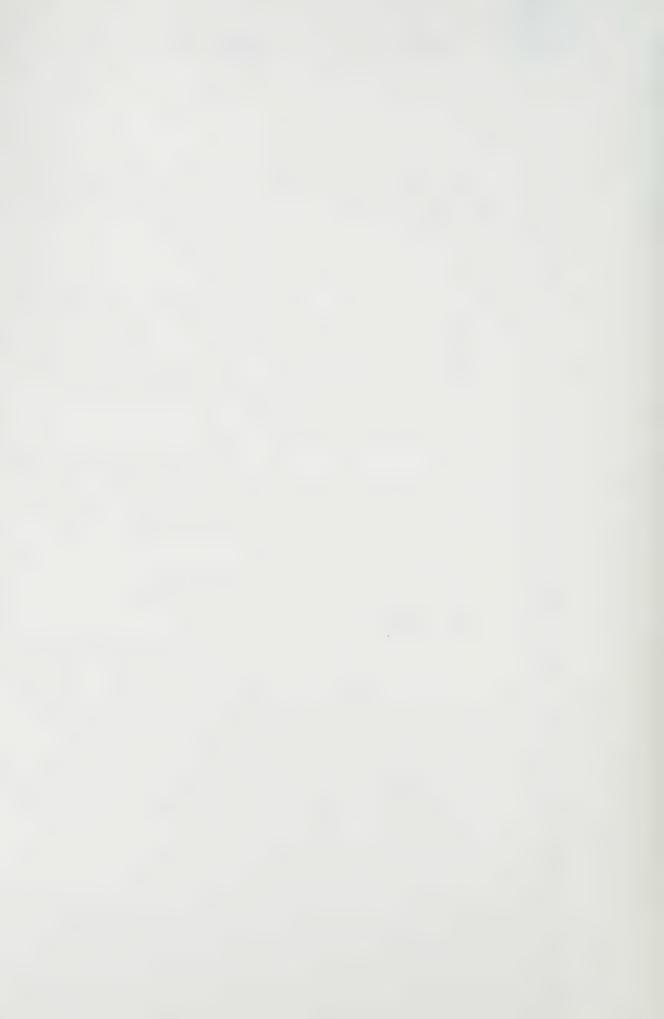
that under the other request section of the requisition form it simply indicates digoxin levels two specimens A and B. I take it we can agree, as you have suggested, that there is no suggestion on the face of the requisition form that any indication was given by Dr. Taylor, at least on this document, that there was some question as to the quality of the sample, is that correct?

- A. Yes.
- $\Omega$ . All right.
- A. The only thing is, this is the Z copy. The requisition form comes in three copies.
  - O. Yes.
- A. The middle copy is the Z copy. That is indicated by the little 'z' in the box at the bottom in the centre.
  - Q. Yes.
  - A. Okay.
- Q. And does carbon paper separate the other two copies, Doctor?
  - A. Yes.
- $\Omega$ . All right, Well can we agree then if there had been any handwriting on the front face copy of the requisition form that suggested



that there was some issue about the quality of the sample, that would likely be on the other copies?

- A. That's correct.
- Q. All right.
- A. The only reason I mentioned the Z copy is that the moment this requisition comes into the laboratory the Z copy is removed. Any comments written by technologists would not necessarily show on the Z copy.
- Q. Do you have any recollection, Doctor, as to whether the original top copy of the requisition form contained any comment at all?
  - A. No.
- $\Omega_{ullet}$  Regarding the quality of this sample?
  - A. Not that specific item, no.
- Q. All right. Doctor, you have told me that by the time the preliminary hearing started in respect of Susan Nelles flow sheets were prepared and I gather there was some suggestion in those flow sheets that there was an issue over the quality of this sample?
  - A. Yes.
- Q. All right. But during the year before that, in January of 1981 when this



sample was being assayed, I take it you can't help us as to how you formed the impression that the quality of this sample was in issue?

A. No.

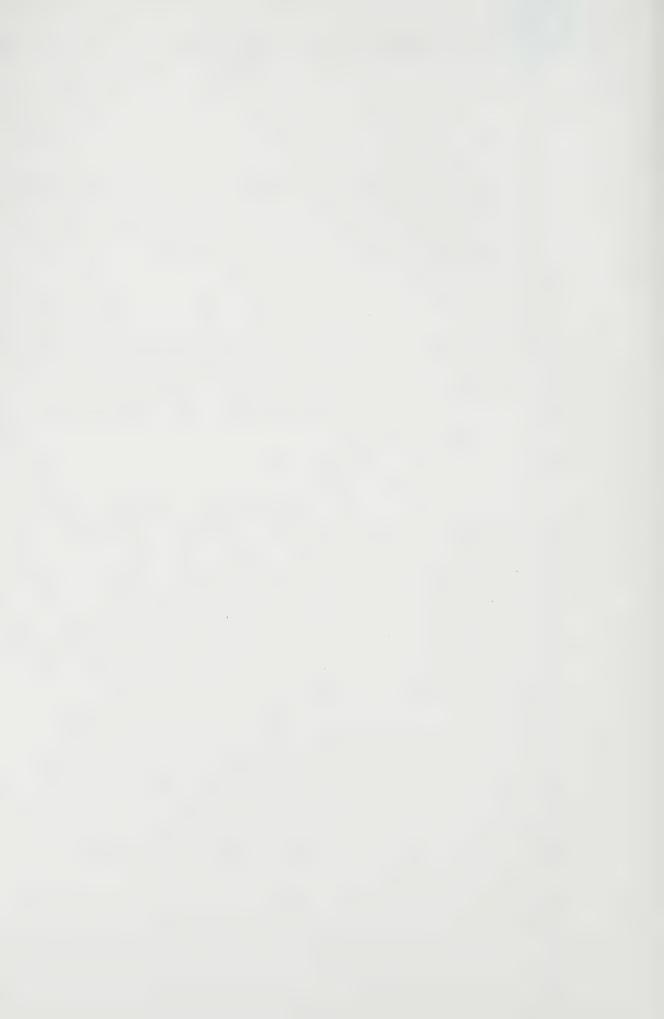
Q. All right. Do you recall specifically, Doctor, having any discussion with any of your technologists with respect to that aspect of this sample at the time it was being assayed?

A. No.

Q. All right. What did you understand, Doctor, the reference to possibly diluted to mean? You have told me that you thought there was some question about the quality of the sample? Did you address your mind specifically to what that might mean? How was the quality of the sample in issue?

A. We usually receive blood and blood serum and that this material contained additional material and fluids additional to the blood in, you know, such a way that the blood would be diluted with whatever material the dilution occurred with.

Ω. Did someone tell you, Doctor, that the sample contained materials other than blood?



All right. Was that something

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then that you deduced from the language of the handwritten note which appeared in the digoxin book?

Α.

0.

Α. Yes.

No.

Q. All right. Doctor, with respect to this particular sample, after the first assay had been conducted on January 12th, do you recall checking the digoxin book and noticing that a postmortem sample had been sent for assay?

Α. I'm sorry, which time are you referring to?

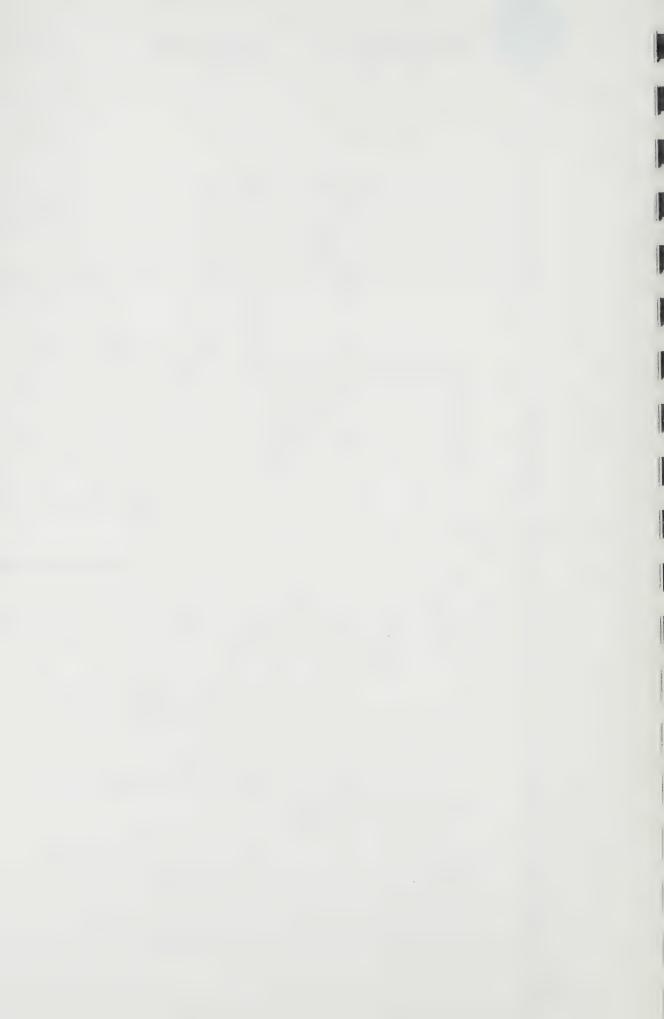
Q. On January 12th when the sample was first assayed, do you recall checking the digoxin book that day and noticing that a postmortem sample had come in for assay purposes?

I believe it was brought to Α. my attention on that day or within the next few days.

> 0. All right.

And I think we did further tests on this sample.

0. All right. That's right, Doctor, and I will come to the further dilutions in a moment that took place. But with respect specifically to the events of January 12th, having



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regard to the fact that you have told us that to the best of your recollection only one other post-mortem sample from pathology had ever been sent to the lab for digoxin assay purposes, were you surprised to receive at this time a sample that clearly was from pathology taken at autopsy?

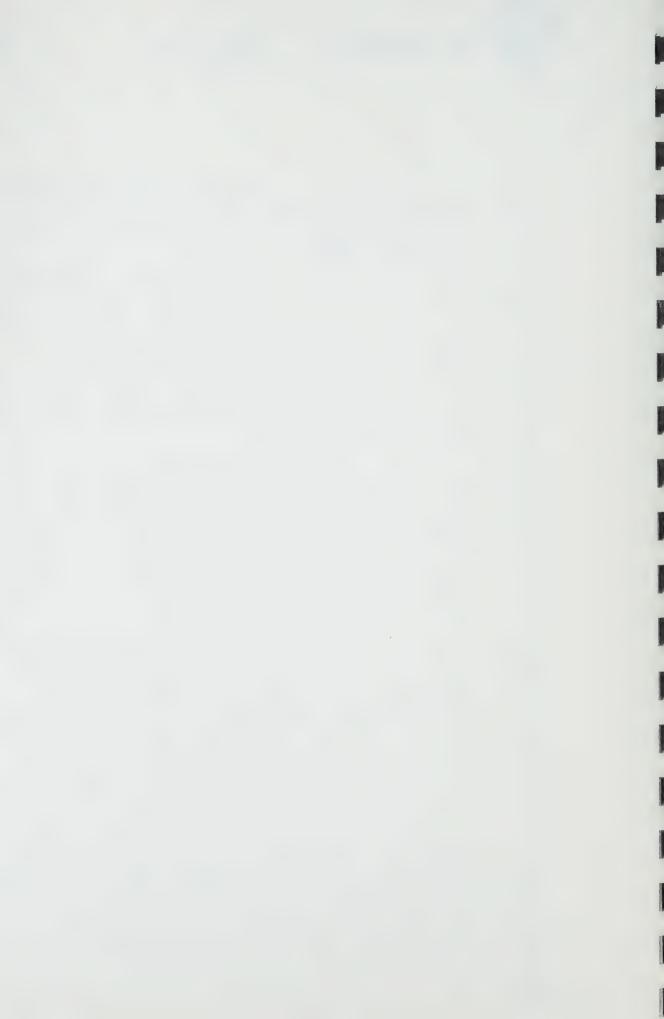
- A. Not really, no.
- Q. What did you understand,
  Doctor, the purpose of doing a digoxin assay on a
  postmortem sample from autopsy?
- A. I didn't question the purpose for which this was being done. I assumed that the originator of the request had a reason for asking us to do the analysis and we would do the analysis.
- Q. Did you contact Dr. Taylor of the Pathology Department to discuss the sample?
  - A. No.
- Q. All right. Did you contact any of the involved clinicians who had been involved in the care of the child to discuss this sample?
  - A. No.
- $\Omega$ . All right. Doctor, as you have indicated ---



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	Α.	Can	I say	also	that	on Monday
arch 12th	, all we	knew r	eally	was th	nat th	e result
as greate	r than 4	.7.				

- Q. That is what the repeat means?
- A. No, the repeat for this sample means that it is, okay, it is more than 4.7. It doesn't mean to say that it is 20 or it is 30 or it is 40 or 50. We have seen greater than 4.7s before, as you would appreciate.
- Q. Well, Doctor, in respect of this sample I take it that on March 12th when the first assay was run you couldn't arrive at a level, you had to dilute it and reassay it to come up with a specific level.
  - A. Yes.
- Q. As I understand it, Doctor, that in fact took place the following day on January the 13th, the sample was again assayed this time on a dilution, is that correct?
  - A. At which time is that, please?
- Q. All right. Well, to assist you Doctor, it appears there was a photocopying error when these digoxin books were reproduced and I have had photocopies made of the entries from the digoxin books for January 13th and January 14th, 1981.



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can recognize them as entries from the digoxin book?

A. Yes.

Q. If we look at the entries

I would ask you to look at them and tell me if you

Q. If we look at the entries for January 13th, 1981, Doctor, it appears that this sample was at that time diluted times two and reassayed, is that correct?

A. January 13th, yes.

 $\Omega$ . All right. And the result at that time was simply the necessity for a repeat assay, the level couldn't be determined?

A. No.

Q. Would I be correct in concluding, Doctor, from that that when it was reassayed at a two times dilution the result was in fact greater than 10?

A. Greater than 9.7.

Q. I'm sorry, greater than 9.7, and it had to be reassayed.

THE COMMISSIONER: 9.4.

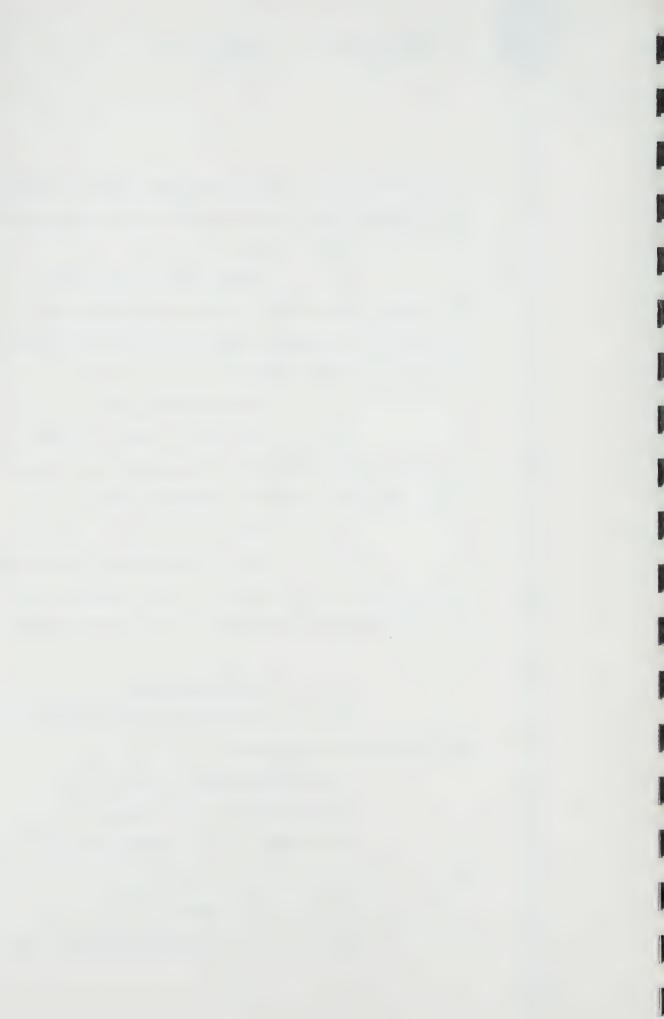
THE WITNESS: I'm sorry.

MS. CRONK: Q. Greater than 4.7 times

A. Okay, yes.

Q. So, it would be greater than

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9.	4	and	it	had	to	be	reassayed?
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A. Yes.

Q. All right. Then it appears, Doctor, that on the very same day it was in fact reassayed again, this time at a dilution of 10?

- A. Yes.
- Q. And at 5?
- A. Can I just go back one stage in that there were samples being analyzed there on the previous day.
- $\Omega$ . Yes, there were, Doctor. I am directing my attention however for the moment to this Sample G89241.
  - A. Yes.
- O. All right. If you take a look at the sample numbers on January 13th it appears that that particular sample was diluted first times 2 and assayed, then it was diluted times 5 and assayed again, then it was diluted times 10 and assayed again, all on January 13th. Am I interpreting those notations correctly?
  - A. Yes.
- Q. All right. And in each case the result was that the level was off the maximum measurement of the test and it had to be reassayed, correct?



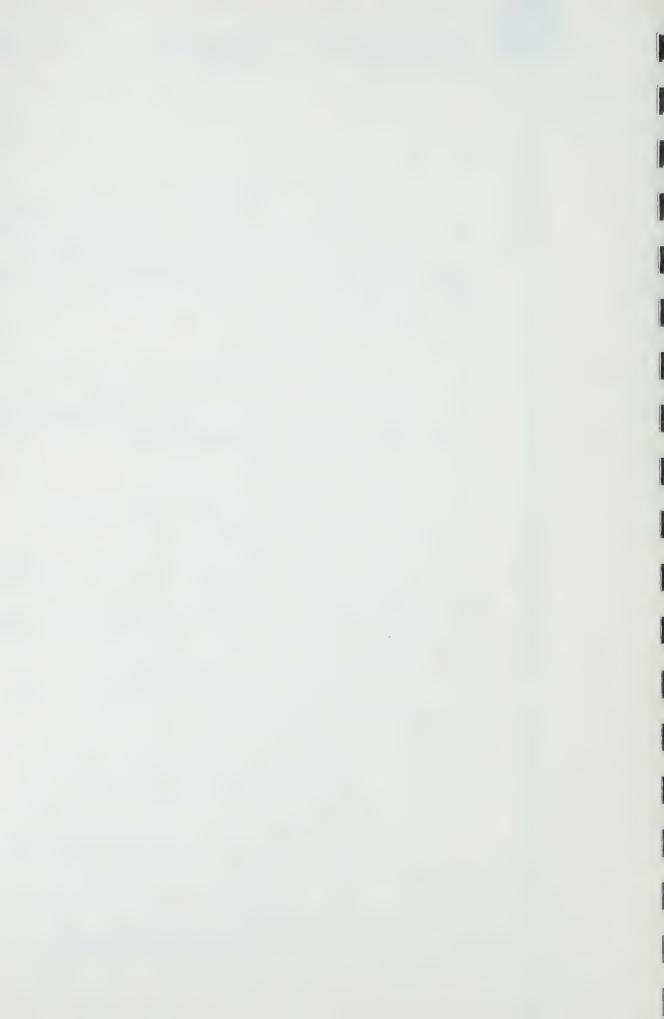
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2	A. Yes.
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5	to January 14th and the same sample was again
	reassayed, again at a dilution of times 10. Do you
6	see that, Doctor?
7	A. Yes.
8	$\Omega_{ullet}$ And once again, as it was
9	the previous day, it was off the maximum measuremen
10	of the scale and had to be repeated?
11	A. Yes.
	Q. And then I would ask you,
12	Doctor, to turn if you would
13	A. I'm sorry, I think I may have
4	been following you a little bit. If we go to
15	Tuesday, January 13th, Sample I, you said that that
6	indicated it had been analyzed times 10.
7	Q. Doctor, to assist you, I am
	looking in the result column.
8	A. Yes.
9	Q. Where it says repeat.
0	A. Yes.
1	Q. And it says times 5 and times
2	10, does it not?
	A. Yes.

Ω.

Does that not indicate that



it was diluted times 5 and then diluted times 10 and assayed?

A. That would suggest ---

THE COMMISSIONER: It is conceivable that that is a question mark, is it, after times 10?

THE WITNESS: I think that is some photocopy from the next page. It looks almost as though here it was done times 5 and somebody decided to repeat it and they advised the person next that they should repeat it times 10. You see, it says repeat times 5 and just above it it says times 10.

THE COMMISSIONER: Just below it. MS. CRONK: Q. Just below it. Doctor, I am showing you the original.

A. Okay.

Q. And beside the word repeat it says times 5 and then times 10. There doesn't appear to be a question mark beside either of those.

A. Oh, yes, okay.

Q. All right. Would you agree with me that that suggests that the sample was diluted on three occasions on that day, on January 13th, first at times 2 dilution and then at times 5 and then at times 10?



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THE COMMISSIONER: It's not times 5, it is greater than 5, isn't it? Isn't it greater than 5?

MS. CRONK: It is an X, sir.

THE COMMISSIONER: Well, isn't that greater than in some circles?

MS. CRONK:Q. Well, it can mean greater than 5 and it can also mean diluted times 5, as I understand it. Perhaps you can help us, Doctor, do you know how many dilutions were done that day?

A. Not offhand, no.

THE COMMISSIONER: I'm sorry, what is it, what does the X stand for again? To me, if you dilute it times 5 you get into some astronomical numbers, do you not?

THE WITNESS: Yes, 25.

THE COMMISSIONER: 3 or 4 hundred,

don't you?

THE WITNESS: No, no.

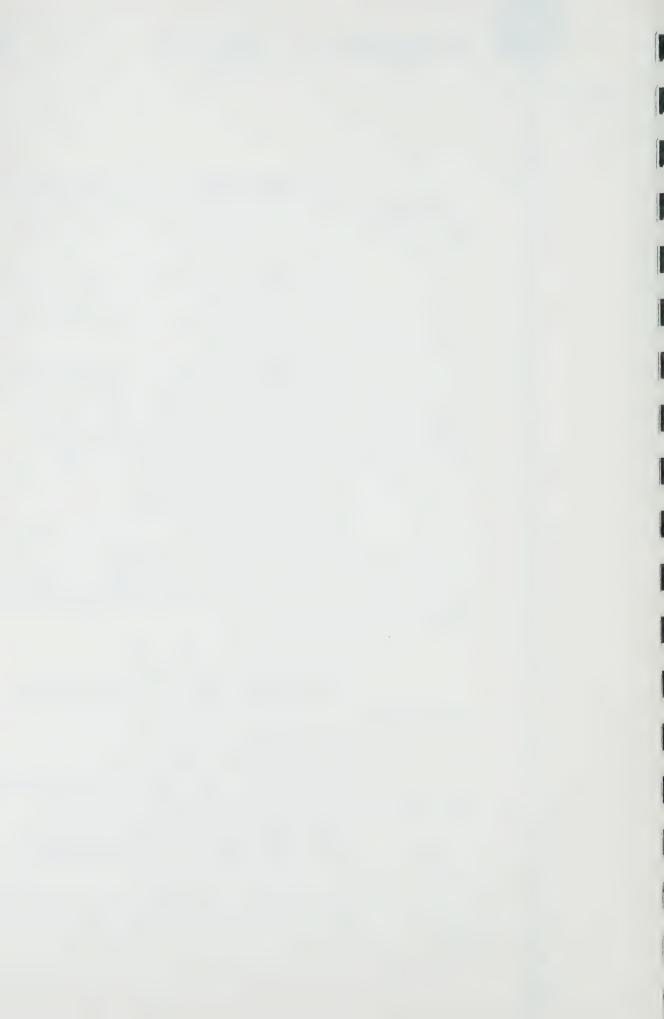
MS. CRONK: No, sir, it would simply mean that if you had a level greater than 4.7.

THE COMMISSIONER: Twice, diluted

MS. CRONK: It would be greater than

9.4.

twice.



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THE COMMISSIONER: All right, let's make it easier for me, let's make it 10. Three times would make it 20.

MS.CRONK: Close to 15. 4.7 times 3.

THE COMMISSIONER: I know, but I want you to do it, to make it easier for me, I am a metrical boy ..... Four times would make it 40 and five times would make it 80, wouldn't it?

MS. CRONK: No, excuse me,

Mr. Commissioner, I am sorry to interrupt but I do think perhaps we have gone astray here and Dr. Ellis can confirm it for me.

THE COMMISSIONER: All right.

MS. CRONK: Q. As I understand it the first maximum measurement, Dr. Ellis, that one might achieve if no fixed level was obtained would be greater than 4.7.

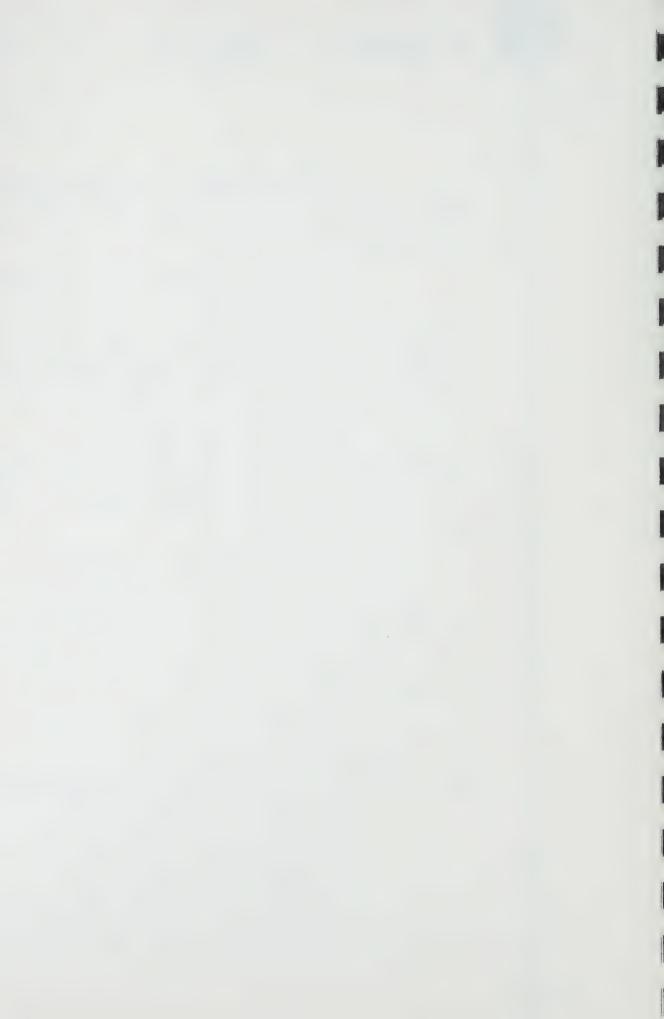
THE COMMISSIONER: That is after January the 10th or something. Just go back to January the 9th, I just want to demonstrate a point.

MS. CRONK: I'm sorry.

THE COMMISSIONER: The first one is 5.

MS. CRONK: All right.

THE COMMISSIONER: The second one is 10, the third one is 20, the fourth one is 40, isn't



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it, the fifth one is 80.

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MS. CRONK: No.

THE COMMISSIONER: The sixth one is 160. Am I not right?

MS. CRONK: I really do think, sir, that that is a little off. May I suggest this to you?

THE COMMISSIONER: All right.

MS. CRONK: And Dr. Ellis can confirm if I'm wrong.

0. Dr. Ellis, leaving aside the case of Janice Estrella for the moment, let's just deal with pure numbers. If a level of greater than 4.7 is achieved the first time you do an assay?

> Α. Ves.

 $\Omega$ . All right. If it is then diluted times 2 the results entered in your books would be 2 times 4.7 equals 9.4. Am I right so far?

> Α. Yes.

All right. If the same sample was diluted again, this time diluted times 5 in five parts, would the result then not be 4.7 times 5 for an approximate result of 20 and change, 25.

> THE COMMISSIONER: Is that right? THE WITNESS: Yes.



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it, sir?

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MS. CRONK: Q. Right. Similarly, if one were to dilute the same sample times 10, in 10 parts, a volume of 10 parts, and the original level was greater than 4.7, the end result would be 4.7 times 10 for 47?

A. Yes, that would be the notation that we would use, yes.

 $\Omega$ . All right. And similarly then if it was diluted times 20 it would be 20 times 4.7?

A. Yes.

Q. All right. Does that clarify

THE COMMISSIONER: Well, it clarifies it but I'm not sure if it is right though. How do you go about diluting, just briefly, I don't want to go into competition with you, I just want to know roughly how you do it? What do you do? First of all, you take this blood and you test it.

THE WITNESS: Yes.

THE COMMISSIONER: And you come out and the best you can do is 4.7 - I would prefer 5 but if you want to use 4.7 that's fine.

THE WITNESS: Whichever you choose.

THE COMMISSIONER: All right. And

then the next time what do you do?



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THE WITNESS: You take, let us say for the sake of simplicity lacc of the serum or ml.

THE COMMISSIONER: Yes.

THE WITNESS: One volume.

THE COMMISSIONER: Yes.

THE WITNESS: And we add one volume.

THE COMMISSIONER: The same amount

of water?

be times 2.

over.

THE WITNESS: The same amount of actually, I say buffer, which is equivalent to water.

THE COMMISSIONER: Yes, all right,

and then what do you do?

THE WITNESS: So, that would then

THE COMMISSIONER: Yes, all right, and then when you don't get it again you just add another one?

THE WITNESS: We would then start

THE COMMISSIONER: Yes.

THE WITNESS: Not with the dilution, we would start over with the serum.

THE COMMISSIONER: Oh, I see.

THE WITNESS: We would then take the 1 ml of serum and add, say, 4 mls of buffer. So, it



is 1.4.

THE COMMISSIONER: Well, all right, that's fine, I'm sure you know what you are doing but if you can run a test on the blood plus the equivalent of water, why can't you run a test on that amount doubled, that is, that plus 3 equivalents of water?

THE WITNESS: Yes.

THE COMMISSIONER: You could do that?

THE WITNESS: Yes. That's what we were doing essentially, yes.

THE COMMISSIONER: Well then, I don't think you got the right result. I may be wrong but I don't think you have.

THE WITNESS: I am sorry, I think the distinction that you are making is that you first of all dilute.

THE COMMISSIONER: Yes.

THE WITNESS: And then you take the dilution and you dilute that dilution again. This isn't actually what we were doing.

THE COMMISSIONER: No, all right.

Well, I will accept your word for it and there is

going to be a lot of cross-examiners afterwards but

I don't know why you say times 5.



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THE WITNESS: Times 5 means that the result, when we obtain it, will have to be multiplied by 5 to obtain the correct result.

THE COMMISSIONER: Okay, I give up, all right. I guess you know what you're doing and I certainly don't but I am surprised.

> THE WITNESS: Well, I'm sorry.

THE COMMISSIONER: No, no.

THE WITNESS: If the real result

is 10.

THE COMMISSIONER: Well, you can't get to, if you make the result 5, you can't get to the reading of 72 except by dilution of, whatever, 5, it would be 14 or 15. You have to do it 15 times, is that correct?

MS. CRONK: 20. Depends on what the original reading was.

THE COMMISSIONER: Well, no, no, but the original number was 5, if it was 4.7 or something but you would have to dilute that many times in order to get to that reading of 72.

THE WITNESS: That's correct.

THE COMMISSIONER: You have something like 14, 15 or 16 or something like that.

THE WITNESS: So, if we were to take



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one volume and add 14 volumes of buffer to that amount and use that material in the same assay and multiply the answer by 15.

THE COMMISSIONER: You actually do

it this way. Assuming that you can read up to 5 the

first time, you take the same amount of this water-like

sustance, add to it, and then you take that same

amount again, again, and again and again and do it

through 14 or 15 assays, do you?

THE WITNESS: No, we would take a volume of the original serum and add 14 times that volume of diluted material.

THE COMMISSIONER: You do that in one operation?

THE WITNESS: Or 20 times.

THE COMMISSIONER: You do it in one

operation?

THE WITNESS: Yes.

THE COMMISSIONER: You take the

serum and add 20 of this water substance?

THE WITNESS: Correct.

THE COMMISSIONER: And do one assay

then.

THE WITNESS: But you would actully add 19. So that the total volume, the total amount



TO TO

would be 20.

THE COMMISSIONER: All right.

THE WITNESS: And this is why on the 16th of January, if I may move to page 2, the ultimate result that we start to produce, it says on the left hand side 3.7 times 20.



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THE COMMISSIONER: I only got one. Have you got another page?

MS. CRONK: We will come to January 16th in a moment, sir.

Q. Right now I would like to be very clear, Dr. Ellis, as to what happened on January 13th with this sample.

The page from the digoxin book suggests possibly one of two things: first of all that the sample was diluted. It is clear it was diluted times 2 with the result that a level couldn't be achieved and that the assay had to be repeated.

A. Yes.

Q. Are we clear on that?

A. Yes.

Q. Then we come to the next entry for January 13th, and in light of what you said a few moments ago I take it there are two possible interpretations for that information. The first is that the sample was diluted times 5 and reassayed on that basis —

A. Correct.

Q. -- without a result being achieved, thus requiring it to be repeated.

A. That would be my assump-

Q. All right.

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A. Because you have mentioned there were two dilutions, but I only have got the one "I". Okay? I have got H, I, J. If in fact there were two dilutions, in other words, four tubes, we should have gone I, J, K.

Q. I take it, then, doctor, in your view there was a second dilution times 5 but not a third dilution times 10?

A. Times 10.

Q. Right.

A. Unless what you say is correct and there was one tube times 5 and one times 10, but I don't think there were more than two tubes being assayed, and my assumption from this notation is it was done times 5 on that particular day, and that a note was left for the person in this notation "repeat times 10". In other words, try it again tomorrow times 10.

Q. All right, doctor.

Then when we come to January 14th we see that it was in fact repeated; this time at a dilution of times 10, and once again a result could not be achieved.

A. Yes.

Q. It had to be repeated.

Is that correct?

A. Yes.





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Q. Then we come to January 16th where you were amoment ago and we find those entries --

THE COMMISSIONER: That is Tab 45?

MS. CRONK: Sorry, you are right,

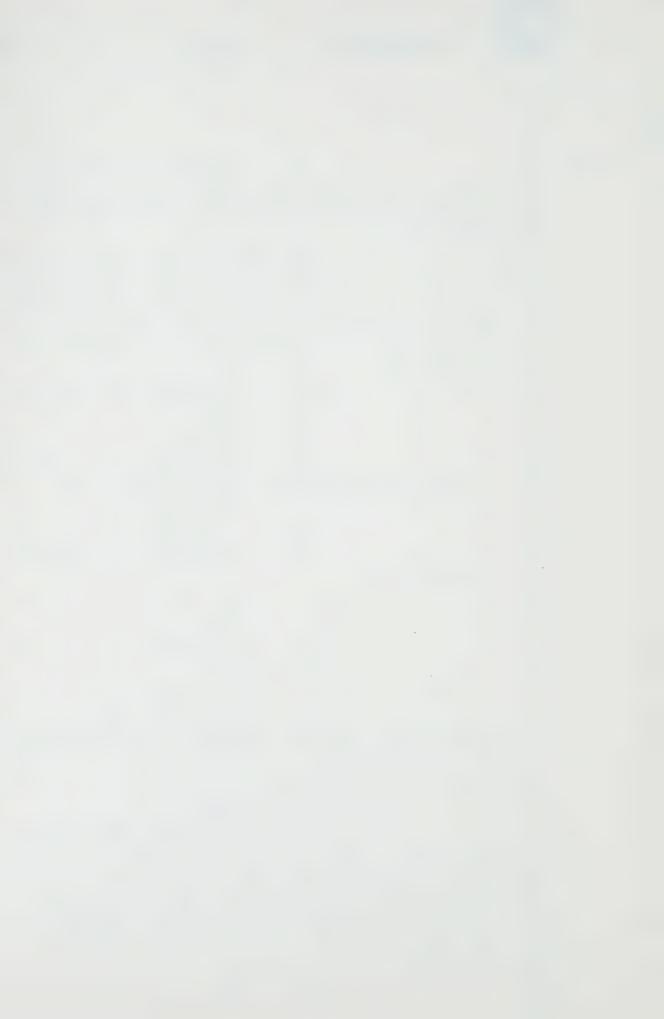
sir. We come then to January 15th but it is at Tab

45, page 2.

- Q. Do you have that, doctor?
- A. Yes.
- Q. On January 15th it appears the same sample was again diluted, again by 10.
  - A. On January?
  - Q. On January 15th, diluted

again times 10.

- A. Yes.
- Q. Reassayed?
- A. Yes.
- Q. That result again is a repeat result, meaning you couldn't get a result; you had to do it again?
  - A. Right.
- Q. So at this stage it had been diluted times 10 on January 14th and it had been diluted again on January 15th times 10, and both results were off the maximum requiring repetition of the assay?
  - A. Yes.



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Q. All right.

Then we come to January 16th and the entry immediately below, doctor, and we see that the same sample was again diluted, this time times 20 --

THE COMMISSIONER: What is the

figure before that? 3.7, is it?

MS. CRONK: It appears to be 3.7

times 20.

Q. Am I reading that correctly,

doctor?

A. That is my --

THE COMMISSIONER: What does 3.7

mean?

THE WITNESS: That would be the result obtained on the calibration curve that would only go up to 4.7, so the actual result they would obtain on that occasion was 3.7 with this very, very diluted material.

MS. CRONK: Q. And then when diluted times 20 there is an indication, not looking at the results category, doctor, but just looking at the entries that appear beside Janice Estrella's name, it appears that the first time it is diluted times 20 the result is in fact 74 nanograms.

Do you see that?

A. In other words, 3.7 times 20.



Q. So that in that case we



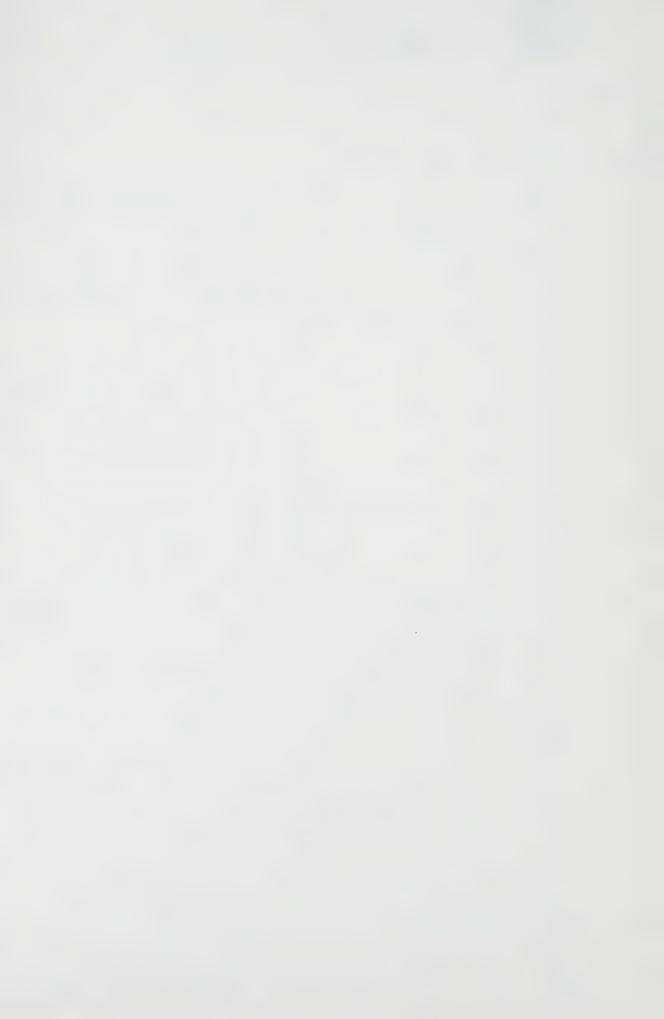
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2	Oh, yes.		
3	Q. I am looking at the actual		
4	number 74.		
5	A. Oh, yes.		
6	Q. Which is encircled beside		
	her name.		
7	A. Yes.		
8	Q. That appears to have been		
9	the result.		
10	A. Yes.		
11	Q. And then if you will		
	bear with me, Mr. Commissioner		
12	THE COMMISSIONER: Yes.		
13	MS. CRONK: $Q$ . If we look		
14	further down the page we see the same sample number		
15	which has again been diluted times 20, and this		
16	time looking at the numbers encircled it appears		
17	that the result was 70 nanograms. Is that correct?		
18	A. Yes.		
19	Q. So that the mean of those		
	two results was taken to report a level of 72 nano-		
20	grams for this sample; is that correct, doctor?		
21	A. Yes.		
22	Q. Am I reading that		
23	correctly?		
24	A. Yes.		
11			



have a dilution twice times 20 of what you have described as very diluted material, and the first time a result of 74 is achieved, the second time a result of 70, and when the technologist or technician was entering that final level in the book the level was chosen to be 72, the mean between the 70 and the 74 reading.

- A. Yes.
- $\Omega$ . Do I have that correctly?
- A. Yes.
- Q. All right.

Now, doctor, with respect to that level of 72 nanograms can you tell me once the assays have been completed on January 16th, was that result - by that I mean the 72 or indeed was the result of 74 or the result of 70 brought to your attention?

- A. Yes, it was.
- $\Omega$ . All right. Had you ever before in your experience, doctor, encountered a digoxin level in the range of 70, 72, 74?
  - A. Not to my recollection, no.
- Q. Were you surprised in this case when a level that high was reported back to you?
  - A. Surprised?



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Did that level startle you? 0.

It appeared to be high, yes. Α.

Well, in your prior 0.

experience, doctor, you have told us that your understanding was as to a therapeutic level for digoxin and a toxic level, this level, the second post mortem sample ever assayed for digoxin in your lab was many, many times that range.

> Yes. Α.

Was it not? Q.

Yes. A.

The level was very high Q.

indeed?

Yes. Α.

Q. When you learned of that

level, doctor, what did you then do?

I instructed my techno-Α.

logist to report the level of 72.

All right. To whom? Q.

In the usual way. Α.

All right. In this Q.

case that would be to whom?

The usual way -- I believe Α.

that we produced -- I have no recollection of a direct telephone call from my technologist to



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Pathology in relation to this sample, and I certainly didn't telephone Pathology at this particular time.

The background is that -- the reason why you telephone results is so the patient does not receive the next dose of digoxin if the digoxin level is high.

This is the second or the first one that was of note autopsy sample; obviously we couldn't help that particular patient and so the urgency with which that result was reported was less than the usual telephone urgency.

> 0. Yes.

And basically my own view of this individual result was that this was analytically satisfactory from an analytical point of view.

I personally did not know why the doctors had ordered it. My interpretation of this result to my staff and in discussions after that were related to very high levels seen in blood - and this is living patients usually -- well, this is living patients. The very high levels that are seen immediately after a dose of digoxin is given, I think we have indicated before that unless you





you there.

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know exactly when that digoxin dose has been given you cannot interpret a result.

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So having seen this incredibly high result I presumed or I assumed that the digoxin dose had been given shortly before death, and nothing more from that.

- 0. Doctor, may I just stop
  - Α. Yes.
- Q. You are explaining -- you told us what your reaction was.
  - A. That was my conjecture.
  - What your concerns were.

You told me first in that regard that you thought the level of the test was analytically satisfactory.

- Α. Yes.
- 0. Do I have that correctly?
- A. Yes.
- Q. And by that do I correctly take you to mean that you had no concerns about the performance of the assay itself?

A. That is correct in that whereas most samples in the laboratory are analyzed, two tubes on one occasion, this result that had been obtained had been analyzed on multiple occasions.



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with that result.

Q. You were then satisfied

that nothing had technically gone wrong with the assay itself?

So from an analytical point of view I was satisfied

A. That was my overriding concern about this particular number of 72.

Q. Did you satisfy yourself that had not happened; that in fact nothing had gone wrong with the assay by virtue of the fact that it had been diluted several times?

A. So many times, yes. Yes.

THE COMMISSIONER: Can I just ask
one question about this dilution.

Do I understand that every time you use a dilution you use up some of the blood?

THE WITNESS: Yes.

THE COMMISSIONER: It can never

be used again?

available for this.

THE WITNESS: That is correct, yes.

THE COMMISSIONER: So you run a

risk in just going up by 2s. You would want to

eventually -- you could very easily run out of blood

THE WITNESS: Very much so.

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keep diluting and diluting and diluting.

If you remember on the first occasion when the A and B were analyzed I think we

had obtained a result of greater than 4.7.

THE COMMISSIONER: So it is probably sensible to bracket it; if you are suspicious of a very large reading it is probably wise to

start with 10 or 20. But you weren't suspicious?

THE WITNESS: No.

THE COMMISSIONER: But you could have easily run out of blood in this instance except I suppose you had such a huge quantity from the pelvic cavity you would never run out?

THE WITNESS: I think the sample requisition stated that there were two samples.

THE COMMISSIONER: Yes.

THE WITNESS: Samples A and B.

THE COMMISSIONER: Yes.

THE WITNESS: That came in with

the same number, one of which seemed to have this association with a possible diluted specimen.

THE COMMISSIONER: Yes.

THE WITNESS: It was only that particular one, if my recollection is correct, only that particular one that had sufficient sample to

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THE COMMISSIONER: 4.7, you didn't have enough blood to go on from there?

THE WITNESS: That is right.

MS. CRONK: Q. Then, doctor --

sorry.

THE COMMISSIONER: I am thinking and that is always a dramatic event in my life. It is the system because clearly it would be better if you are going to be dealing in figures like this and you have only a limited amount --

THE WITNESS: Yes. You start with a very, very tiny amount.

THE COMMISSIONER: No, but if

you can dilute -- I don't quite know why -- if you

just need that amount of blood, to dilute as many

times as you like, but you only do it once. If you

were to dilute it 10 or 20 times would you not still

get an accurate reading instead of diluting it twice?

I just don't understand why the twice.

THE WITNESS: I appreciate the point you are trying to make.

You are saying that a certain amount of blood arrives in the laboratory.

THE COMMISSIONER: Yes.

THE WITNESS: And we will analyze



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a part of it neat.

THE COMMISSIONER: Yes.

THE WITNESS: A part of it as

it stands and throw it away. Okay. Because --

THE COMMISSIONER: You never use

it again.

THE WITNESS: We can never use it again and in fact as part of the assay it gets consumed.

THE COMMISSIONER: Yes.

THE WITNESS: It gets thrown away.

THE COMMISSIONER: Yes. You only

have got an opportunity for one more assay.

THE WITNESS: This would depend

on the amount received.

THE COMMISSIONER: All right.

Let's say you get enough for two; you get enough for two, and I have seen this happen. In many cases you have said greater than 10 and we

can't go any farther.

THE WITNESS: Yes.

THE COMMISSIONER: I just ask
why under those circumstances you don't dilute 20,
30, 40 times to make sure you get one more reading
that will tell you what the answer is.

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THE WITNESS: Yes. Basically because our experience is that in 98% of the cases simply by doing a single-shot dilution of 50 microlitres into two tubes we get the answer.

THE COMMISSIONER: You do it once and you don't get the answer --

THE WITNESS: Right.

THE COMMISSIONER: -- that might

make you suspicious?

THE WITNESS: Yes.

THE COMMISSIONER: And you say there is something wrong with this blood; there is too much digoxin in it. And then what do you do? You decide you will do it once more. But really what I am getting at does it make any difference as far as the accuracy is concerned whether you dilute it twice, four times or 20 times?

THE WITNESS: Yes, in a sense it does because if you dilute it 20 times the level is only just greater than 5, but then whatever inaccuracy there is in that result that is obtained you will multiply that inaccuracy by 20.

If you dilute it on the other hand times 2 whatever inaccuracy there is associated with that result will be increased times 2 by the dilution



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factor, so the best result we can get is a straight assay.

 $\mbox{MS. CRONK: } \mbox{$\Omega$.} \mbox{ And by straight} \\ \mbox{assay, doctor, you mean neat?}$ 

- A. Neat, yes.
- Q. Without any dilution at

all?

A. Yes. And in relation to my 98% of cases that we can do straight I would say that, guessing in terms of numbers, that we then go to 99.5% on the ones that we can get 1 in 2.

Okay. And the numbers that we have to dilute 1 in 20 or --

- Q. Are very rare indeed?
- A. Very rare indeed.
- Q. And in this case, doctor, we know that that happened and you have told us that once the result, the level, was made known to you you first satisfied yourself that analytically the assay had been performed correctly?
  - A. Yes.
  - Q. You didn't have any

concerns on that level?

A. Yes.

THE COMMISSIONER: If I could just



BB16 2

ask one more question while we are on this subject and then I will keep quiet.

If you look at Exhibit 45 from the preliminary inquiry, you look at Item C, Item G, I take it those were two separate assays requiring two separate vials or whatever they are of blood.

Is that right? Page 2.

THE WITNESS: Page 2, yes.

THE COMMISSIONER: You see C,

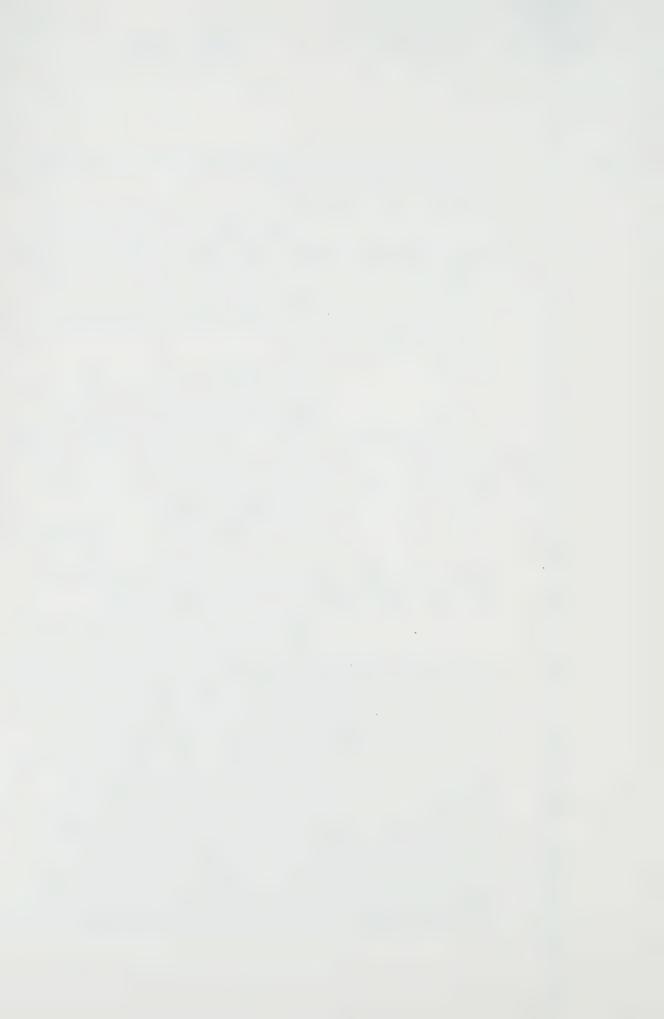
in the bottom part of it, C and G were assays of the same sample but they were separate -- not samples --

MS. CRONK: Assays.

THE COMMISSIONER: -- separate assays but they used separate blood? Is that correct? You couldn't use the same blood?

THE WITNESS: In making a 1 in
20 dilution we may have ended up with quite a large
volume that could have been used for both those -both those independent assays from then on.

MS. CRONK: Q. May we be clear about this, Dr. Ellis, and the Commissioner's question, as I understood it all of those assays that were done on the 15th and on the 16th of January were on the same sample of blood, it was the same blood; it was just a different part of the



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sample?

THE COMMISSIONER: Yes.

Α. Yes.

MS. CRONK: Q. Is that correct?

That is correct.

0. You are not talking about

different blood. It was the same sample, same blood specimen, and it is just that in each case you were using another part of it. You weren't using the same part.

Α. Yes. On sequential days we would use a separate part of that blood.

> 0. That is right.

Α. On the 16th of January my technologist would have two options: to make a dilution 1 in 20 and analyze it effectively four times to give him C and G, or to take one part of the blood and dilute it times 20 and assay it and take another part of the blood sample, dilute it times 20 and assay it.

> That is what he chose to Q.

do?

I don't know which he Α.

chose to do.

0. All right. It appears,

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doctor, from the entries on January 16th, however, that there were two assays at 20 times dilution run, does it not?

A. Yes.

Q. Does that not suggest that one part of the sample was diluted times 20, was assayed, resulted in a level of 74, and then another part of the specimen was again diluted times 20, again assayed quite separately from the other one, and this time resulted in a level of 70?

A. Yes. The subsequent assay was quite independent of the other one. The G assay was quite independent to the C assay.

Q. I'm talking only about G. Oh, I am sorry, C and G, yes.

A. Okay. What I can say is that those are independent assays, almost like a different patient.

THE COMMISSIONER: Different blood, too, because particularly if it is contaminated would they not be different blood?

THE WITNESS: No, I don't think so.

THE COMMISSIONER: I don't know,
but if it was contaminated wouldn't it be contaminated
in one part of the sample more than another or would



BB19 2

it all be mixed up?

THE WITNESS: It would have been mixed up, yes.

of any part of it would be the same?

THE WITNESS: It should have been dispersed, yes. But I cannot tell whether separate portions of the same blood sample were taken for Analyses C and G, but I believe from the analysis point onward, from the two tubes onward right through the immunoassay procedure effectively four tubes were being handled in relation to that sample.

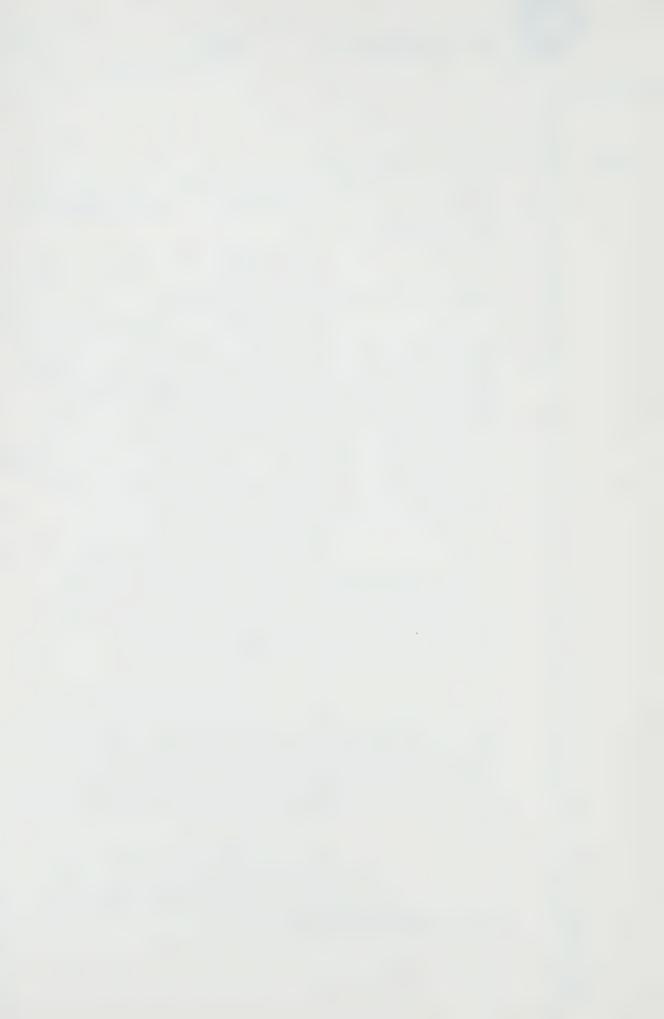
MS. CRONK: Q. Yes. And just to be very clear again, you were satisfied that in consideration of the results the assay as it had been performed was performed correctly?

A. Yes.

Q. All right. And you have told us as well, doctor, that you had a concern with respect to this level once you were made aware of it, that there might have been a problem in terms of the time --

A. Well --

 $\Omega_{\bullet}$  Just if you could wait for the question, Dr. Ellis.



Ellis dr.ex. (Cronk)

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Α. But you said I expressed concern, did you say?

I am sorry. You were explaining earlier your reaction to this level and you told me two things: first that you thought it was analytically satisfactory.

- That is correct.
- 0. All right. Secondly

I understood you to say that you thought it was high and you discussed with your technologist at the time the possibility that the sample which had been assayed had been taken in too close proximity to the time at which the last dose of digoxin had been administered?

- Α. Correct.
- Do I understand that? Q.
- Α. Yes.
- Q. Was that not a concern in your mind in terms of trying to arrive at an explanation for this level? I put it no higher than that. That was one of the things that you thought might explain this level?

That was one of the things that I felt might explain this level.

> Q. All right.



BB21 2

A. I regarded that as the most likely explanation.

Q. All right.

A. To the point of dismissing other possible reasons why that might have occurred.

Q. All right.

Then let's examine what you thought was the most likely explanation and that is the time interval between when the last dose is given and the time when the sample itself was taken.

From your earlier evidence, doctor, we have looked at the assays that were conducted on January 8th on this child, the assays that were conducted on January 9th and the assays on January 7th, and you told me that on January 7th on a different sample, also a blood sample from an artery, the level was greater than 5 but it was reassayed the following day and a result of greater than 9.4 or greater than 10 was achieved, but that that greater than 9.4 or greater than 10 result was not reported because the reporting of the greater than 5 level would have been sufficient to put, I took it, the clinicians on notice that digoxin should be held.

A. Yes.





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Q. Do I have that correctly?

Yes, that is correct. A.

Q. All right.

The child was showing some A. evidence of - I am sorry, the child was - appeared on the basis solely of the results to be going through an episode of digoxin toxicity insofar as you can define that from the results only.

0. The level of greater than 5 that was in fact reported was well above what you understood to be the threshold of the toxic range?

> A. That is correct.

Q. That is on January the 8th and January the 9th?

> Α. Yes.

And you have also told me that on January the 9th, I am sorry, January the 8th, another sample was assayed and this one had a result of greater than 4.7. It is well assayed the next day on January the 9th, and this time a level of 7.8 was achieved, but you told me that 7.8 level was not reported to the ward, again for the same reason that because the day previously a greater than 4.7 level had been reported, that level, the 4.7 would be sufficiently high to alert the clinicians that digoxin



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should be held; do I have that correctly?

A. Yes, and because a subsequent sample I think was being analyzed, a fresh sample as opposed to yesterday's.

about, the one that resulted in a level of greater than 4.7 was assayed on January the 8th, was reported by telephone on that day, you have told us. As I understood your evidence that would have been sufficient to put the clinicians on notice that digoxin should be held; do I have that correctly?

A. If your recollection of these events is correct, yes.

Q. No, I am talking about your evidence this morning, Doctor?

A. Well, if that is what I said this morning with the books in front of me then that is okay.

Q. My question to you at this point, Doctor, is with that in mind --

A. Yes.

Q. -- by January the 9th there has been two levels reported to the ward, one of greater than 5, correct?

A. Yes.



correct?

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Q.	And	one	of	greater	than	4.7

- A. Yes.
- Q. I am sorry, was that yes?
- A. Yes.
- Q. Both of those levels, Doctor, were outside, beyond the threshold of the toxic range as you understood it?
  - A. Yes.
- Q. In those circumstances did you assume, Doctor, that digoxin would have been held on this child?
  - A. Yes.
- Q. If that be the case, Doctor, and you then received another sample on January the 11th, which was then assayed a number of times and resulted in a level that we have seen of the mean result of 72 nanograms, how could you then assume that if the sample had been taken too close in time to the time at which the dose had been administered if you had been presuming that digoxin had been held?
- A. Isn't there one element in this that you are forgetting, and that element is that the last result was not greater than 4.7 but was reported as 4.7. In other words, we saw a peak and we saw it



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coming down, isn't this the situation?

TORONTO, ONTARIO

O. Yes, that is correct, Doctor.

The last result you have just mentioned was greater than 4.7?

0. Yes, and then on the 9th one of 4.7 is reported.

> 4.7 ---A.

THE COMMISSIONER: Miss Cronk, where is that, I am getting mixed up with this Exhibit 45 and Exhibit 46.

MS. CRONK: I am sorry, sir.

THE COMMISSIONER: Could you tell me -

I take it ---

MS. CRONK: This is under Tab 46, sir.

THE COMMISSIONER: Yes, I know. It starts on the 15th of January, this is Exhibit 45 and it seems to go on to the 24th of March, which is of course a very important day. The other one starts at the 17th of October and seems to go on ---

MS. CRONK: The 17th of October, 1979, and goes on to January the 12th, 1981.

THE COMMISSIONER: Yes, that is right, I am sorry.

MS. CRONK: Q. Doctor, if I can refer you to page 169 at Tab 46.





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A. Yes.

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TORONTO, ONTARIO

Q. And may we examine again the events before the postmortem sample, right.

A. Yes.

Q. You have three levels reported to the ward; the first is a level of greater than 5, that is an assay result achieved on January the 7th.

- A. Okay.
- Q. That is on page 167, Doctor.
- A. Oh, okay, yes.
- Q. Is that correct?

A. I wasn't taking exception to those points, right. I was just taking exception to the fact that this had been a very high result of greater than 10 at one stage, it had slowly come down to 7-point-something and by the Friday the 9th of January, on the second page, 169, the result that we were actually reporting then is 4.7.

Q. That level, Doctor --

A. No greater than 4.7.

Q I accept that, Doctor. I just wish to be clear about what your concerns were?

A. Well, my concerns are that we have seen an episode of elevated digoxin level that appears to be coming down, okay.



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Į.	Yes,	Doctor	

And eventually that particular A. digoxin level if the child's metabolism is okay, will come back into the normal range at some point.

Doctor, is the level on January 0. the 9th the last antemortem level reported as 4.7?

> Α. Yes.

That level I take it we can agree is beyond the threshold of the toxic range as you understood it?

It is, yes.

It is well beyond the 3.5? Q.

A. That is correct.

0. In those circumstances, would you assume at that point that digoxin would continue to be held with respect to that child?

A. On that day, yes, unless there were overriding clinical indications of starting it up again.

If I understand your evidence correctly, Doctor, given that you were concerned when you learned of the level of 72 nanograms that the sample may have been taken in too close a point of time to the time of the last administration of digoxin?

A. No, again you said I was





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concerned but, I wasn't "concerned but", I rationalized it on the basis that this had probably happened. I wasn't concerned at this particular stage with this result, it wasn't my concern.

All right, Doctor, I am sorry.

It was a sample supplied to the laboratory by a pathologist who has the responsibility of determining the cause of death, and who happened to in the course of his investigation to send an additional sample to us. Our responsibility then, as I saw it at that particular time, our responsibility is to produce a result on the basis of the sample that he sends us and to send it back to him. Our responsibility is not to be concerned with anything, you know.

Now admittedly in a few months' time we were starting to get concerned, but there was no concern on my part in relation to this result at that particular time.

I didn't intend to suggest that there was concern about anything sinister, Doctor.

> Α. No.

I am concerned only to explain how that level could have resulted. As I understood your evidence you thought that one possibility, and





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you have said the most likely explanation you thought, was that that level of 72 could have resulted because the sample was taken too soon after the last dose had been given, do I have that correctly?

> Α. Yes, you have that correct.

0. Now with that in mind, were you then assuming, on January the 16th when that level became known to you, that the child had again received digoxin during life, prior to death, notwithstanding that the three antemortem levels of which you were aware were above the threshold amount of the toxic range?

Okay. How do you put together every single detail of the previous week in the way that we are putting it together now?

All right, Doctor. Did you, Doctor, when you were examining possible explanations for this level, contact Dr. Taylor or anyone else in the Pathology Department, to determine if in fact the sample had been taken too close in time to the date of the last dose?

No, I didn't.

And I take it then, Doctor, that on January the 16th when these possible explanations were going through your mind, you were





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not aware of the fact that Janice Estrella did not receive digoxin for four days prior to her death?

> A. I am sorry?

I take it on January the 16th you were not aware of the fact that Janice Estrella had not, as it happens, received digoxin for four days prior to her death, you were not aware of that?

I wasn't, no.

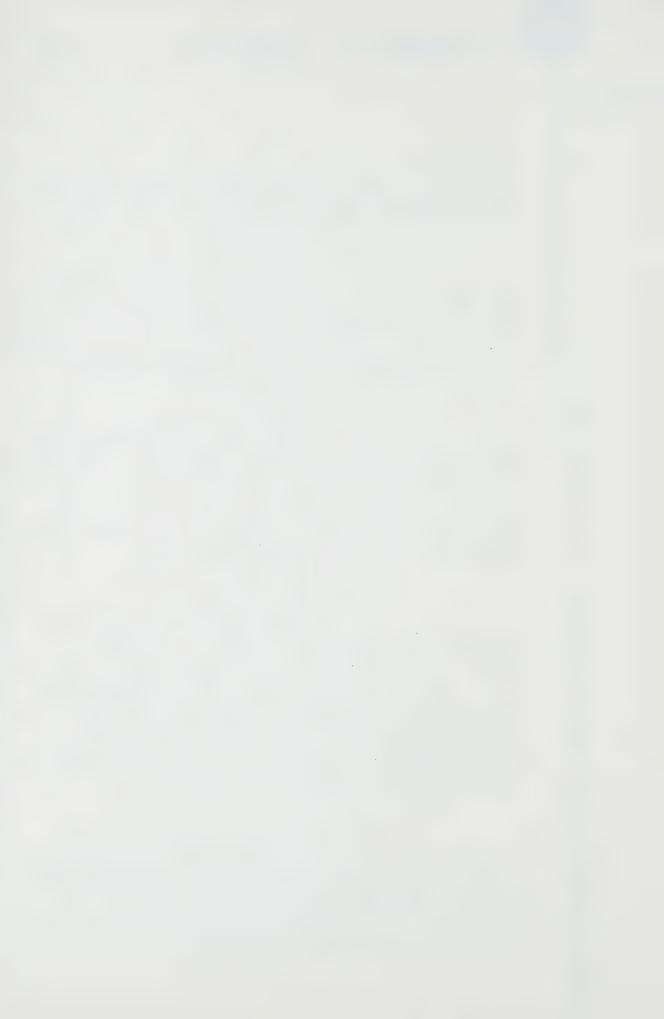
Doctor, you indicated as well that a second assay was being conducted on a different, a separate sample at the same time that this sample originally was assayed. I would ask you again to look at page 169, and that is Tab 46, Doctor.

> A. Yes, thank you.

Doctor, we see on January the 12th that the second sample, Sample No. GA9246 was as well received from Pathology and it appears to be a sample taken on January the 11th and the assay result was greater than 4.7, right, that is the one to which you drew our attention previously?

> Α. Yes.

And there is as well, Doctor, a handwritten notation, again beside the name Janice Estrella, indicating that that sample was post mortem (from vein), do you see that, Doctor?





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A. Yes.

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Doctor, was it your understanding on January the 12th when this assay was done that this was a sample of postmortem blood obtained from the vein, did you know that then when it was being assayed?

Α. Well, it also says postmortem blood, doesn't it?

> 0. Yes.

Ά. So then or around that time.

That was drawn to your attention?

That's right.

0. There is no indication with respect to that specimen, Doctor, in your digoxin books that the specimen was possibly diluted, is there?

A. No, this in contrast to the possibly diluted, a notation "from vein" was given.

All right. Was there any issue or question of which you were aware at the time that that second sample, the one from the vein might be possibly diluted?

> A. No.

0. And Doctor, with respect to those two levels, dealing with the events of January the 12th, you then have one sample which has resulted in a level of greater than 4.7; was the quantity of



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the sample sufficient to permit further dilution on that sample? To help you it is my understanding it was not?

- A. GA9246?
- Q. That's right.
- A. I don't think there was sufficient otherwise we would have attempted to do it.

Q. So on that day you have one fixed level of greater than 4.7, that is off your maximum, and you have another but you don't know what the amount is, the fixed level, you don't discover the actual fixed level of that second sample until some four days later on January the 16th when it is clear as a result of the assay, that the level was in fact 72 nanograms; do I have that correctly, Doctor?

A. Yes, that our result was 72.

On January the 12th when the first fixed level was available for reporting, the greater than 4.7, was that orally reported to the Pathology Department?

A. I don't think - it wasn't by me to my recollection. There was the outstanding order, if you like, that the results first of all would be telephoned. Because of the kind of unusual nature of this particular sample, I don't know for sure that that occurred.



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		Q.	What	was	the	unusual	nature	01
this	sample,	Doctor?						

Well, because it was from Pathology and so we could no longer stop the next digoxin dose, which was the major overriding reason for telephoning the result.

I see, so I take it you don't know whether this one that was greater than 4.7 was in fact telephoned to Pathology?

I don't know whether my staff A. did or didn't, and I am sure they probably won't be able to remember either.

Q. I take it you don't recall instructing them to do so?

> A. No.

And you yourself did not do so? Q.

A. No.

Then we come to January the 16th, 0. Doctor, and the results of both of those series of assays, if I can describe it that way, were available to you and you know you have one level on one sample of greater than 4.7 and a level of 72 on another discrete, separate specimen?

> A. Yes.

Q. At that stage ---





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A. Yes, of unknown quality.

0. Because of the possible dilution

issue?

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A. Yes.

Did you at that stage, Doctor, consider it appropriate to contact the involved pathologist to determine whether or not the sample that resulted in the 72-nanogram level had been diluted?

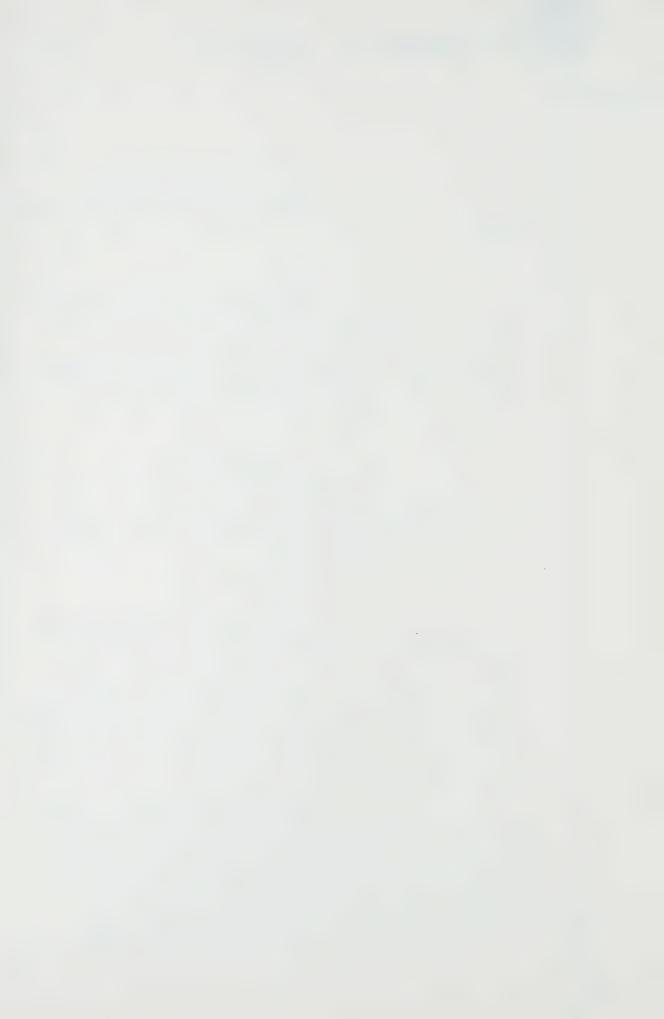
Had been diluted?

0. By a contaminant? Was it at that stage considered by you appropriate to do that, to contact the pathologist?

> Α. I didn't do that.

0. Did you at that stage have any discussion with any of the clinicians who had been involved in the care of the child during her life to determine in fact what the history of the administration of digoxin had been, and what the doses were that had been administered to her?

I don't believe I did, no. Can I say that in Biochemistry we receive a large number of samples during the day. If there is anything we can do to help the child when the result becomes available by making telephone calls, then we would





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attempt to do so, but in this particular case ---

0. There wasn't.

There wasn't as far as I was concerned. We can't telephone every single result, even if it is unusual but - I am sorry, except in relation to digoxin. We have to make some assumptions in the overall operation of the Department. One assumption is that if somebody sends you a specimen they have some reason for sending you that specimen. That is one assumption we make.

The second assumption that we make is that when you produce a result for them they are going to have the knowledge, or some way of knowing what that result means in the particular context in which they requested that sample.

The third assumption we make is if they don't know that, if they want help, then they phone you and they say, hey, we don't believe this result; or they phone you and say, what do you think about this, have you seen one like this before? So, my main concern was as accurate as it is send it out then, let them figure out what it means, I can't tell them what it means.

Doctor, in this case, given that those were the assumptions at the time that were





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necessary in your view to run the department, in this case after those two levels were available, that is by January the 16th those were available, I take it that in due course a Biochemistry clinical printout was made available and forwarded to Pathology reporting those results?

A. I assume that that happened. that was the procedure.

Q. Were you then contacted at any time during the month of January, up to the end of January, by anyone from the Pathology Department to discuss either or both of those levels?

Not to my recollection.

During the month of February 0. were you contacted by anyone from the Pathology Department to discuss either or both of those levels?

A. I believe the only contact that we had followed the death of Pacsai.

Q. And that would be after March the 12th then, 1981, that is the date that Kevin Pacsai died, right?

> A. Yes.

Doctor, up until that time from January the 16th through until March 12th, 1981, do you recall being contacted by any clinician, any



TORONTO, ONTARIO

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cardiologist in the Hospital, to discuss either or both of those two levels on Janice Estrella?

A. I don't recollect any conversations in relation to that.

Q. I am sorry?

A. In relation to the autopsy samples you mean?

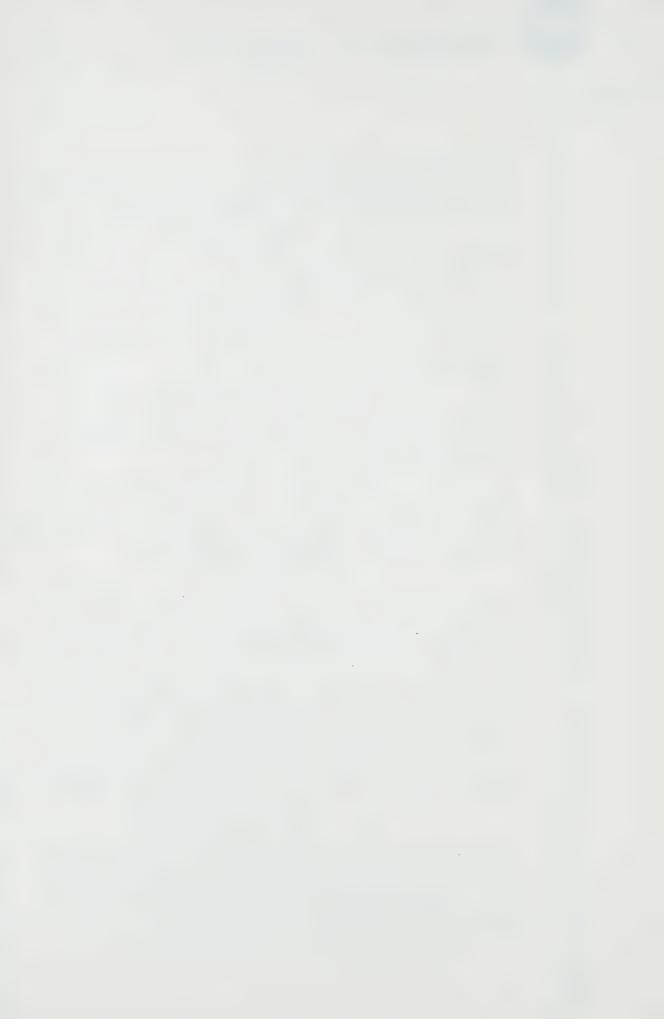
Q. I am talking about the two autopsy samples, the level of 72 and the level of greater than 4.7?

A. Yes. You see, those results originated from the Pathology Department so they would be sent back to the Pathology Department.

Q. I understand that, Doctor. My question was merely whether or not you, or to your knowledge, any of the technologists in your department were contacted by any of the cardiologists involved in the care of the child during life to discuss those levels at some point subsequent to the reporting of those levels to Pathology? I take it your answer is no?

A. Not to my knowledge.

Q. And more specifically, Doctor, were you contacted at any time up to March 12, 1981, by Dr. Robert Freedom of the Cardiology Division to discuss either or both of those levels?



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A. Was that prior to the death of

Q. Yes, March 12 is the day that Kevin Pacsai died?

A. I don't recall any conversation that we might have had.

 $\mathbb{Q}$ . And Doctor, with respect to the vein sample which resulted in a level of greater than 4.7 --

A. Yes.

Q. -- with respect to that sample,

I take it that we can agree that because the only

result that was available on the assay that was

conducted was the result of greater than 4.7, that we

cannot be certain what in fact that level was?

A. No.

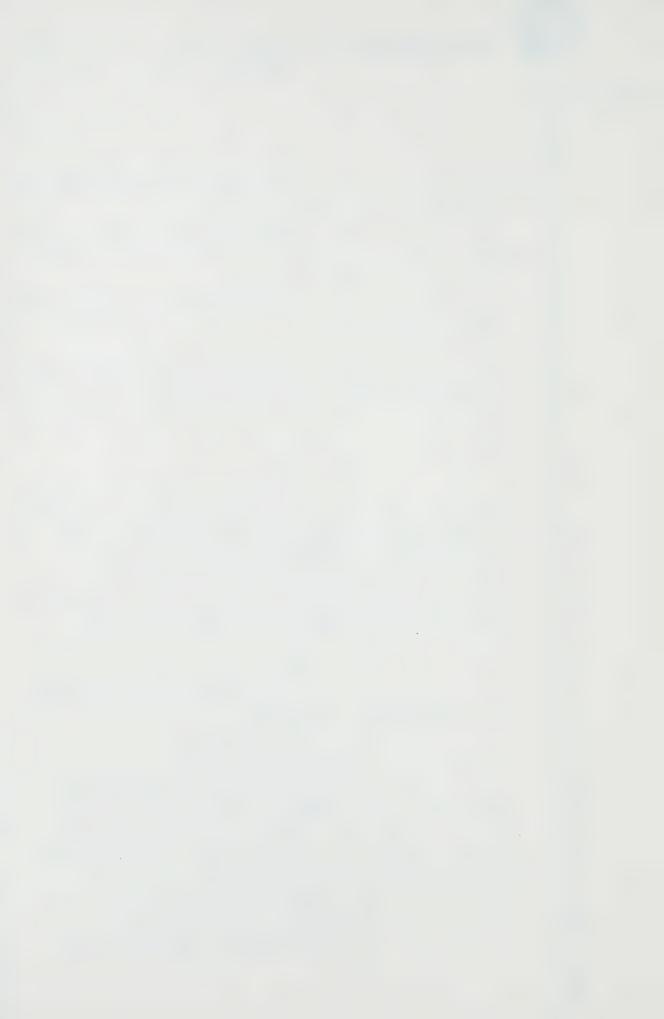
 $\ensuremath{\mathbb{Q}}.$  It was simply off the maximum of the recording of the test?

A. That is correct.

THE COMMISSIONER: Was there any indications in the computer printout, or any place else that you couldn't do another assay? I am looking at page 158 which I guess of the ---

MS. CRONK: Exhibit 91, sir.

THE COMMISSIONER: Exhibit 91. Was





TORONTO, ONTARIO

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sample?

sample.

there any indication that you couldn't do any more than that? I think it was Dr. Taylor who assumed there would be another report on that.

THE WITNESS: On the second blood

THE COMMISSIONER: That is the vein

THE WITNESS: The vein sample? Does it say NSQ to repeat on the bottom of the report?

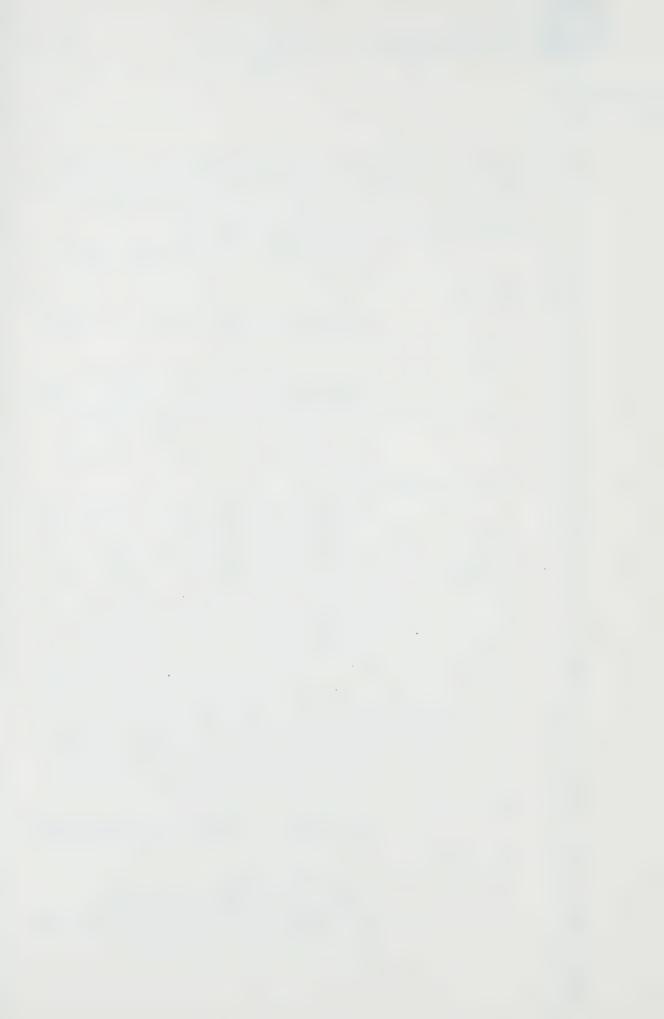
MS. CRONK: No I believe it is the Commissioner's point ---

anything on the computer printout as to whether there is going to be another one or not. Dr. Taylor said that he - I am not too sure; I think he may have decided it was just one sample that was given but he expected that the 4. -- he didn't look, I can pretty well understand, or take in the specimen number, but he saw presumably shortly after the 13th of January, shortly after - do you want to turn to page 158 of Exhibit 91?

 $\label{eq:MS.CRONK:} \mbox{I am not sure the Doctor}$  has it, sir.

THE COMMISSIONER: I am sorry.

MS. CRONK: Mr. Registrar, could you





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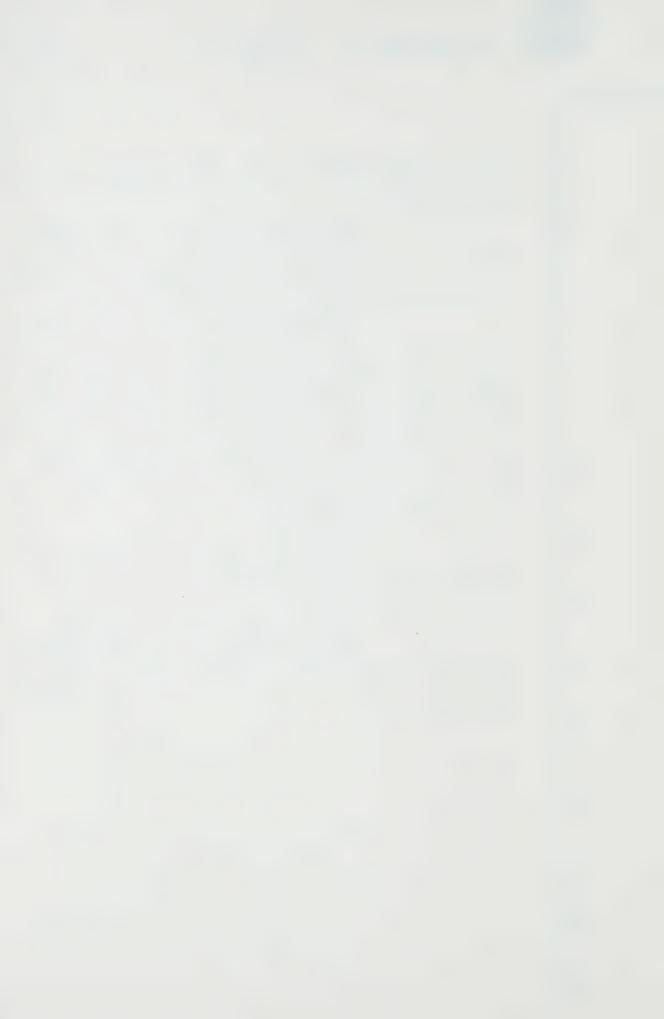
give Dr. Ellis Exhibit 91, the medical record of Janice Estrella.

THE WITNESS: Looking at our digoxin book if you say that the computer printout didn't have that notation I can well understand why it didn't.

THE COMMISSIONER: What happens, you see, is that it gets - on page 158 you will see the greater than 4.7, and then go back to page 157, it gets 72 some days later. Apparently page 156 there is also a level of 72. I don't quite understand that, both seem to have an asterisk, so they are both reported for the first time.

MS. CRONK: The two results, sir, on this sample are the two reports that deal with the greater than 4.7 and they are at page 159 and 158.

THE COMMISSIONER: Yes. But neither of those as I understand it indicate there is going to be another ---



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Can you perhaps tell me. I assume that the asterisk being on page 158 that first report came with the computer printout dated the 13th of January, '81. Am I correct on that?

THE WITNESS: Yes.

THE COMMISSIONER: 4.7.

THE WITNESS: Yes.

one, or perhaps the second, third or fourth, I don't know, page 159, I don't see anywhere there an indication that there is not sufficient quantity to make another assay. If you look at page 156 and 157, they seem to be identical reports except different dates. Do you see the report of the 72 coming in presumably for the first time?

THE WITNESS: Yes.

THE COMMISSIONER: Dr. Taylor, as

I understand it, really assumed that the 72 and the

4.7 were the same and he expected after the greater
than 4.7 to have another and then of course when
he got the 72 he decided that that was not a valid
return. All I'm asking really, is it part of your
computer printout to tell that you can't go any
higher than the 4.7. I mean, does that happen.

If it doesn't happen that's fine, it wouldn't happen





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here, but does it happen sometimes? You put not sufficient quantity if you can't make any test.

THE WITNESS: If you can't do any test at all, right.

THE COMMISSIONER: If you can't dilute you don't put anything in.

THE WITNESS: If we use all the sample and obtain the result of greater than 4.7 and that's as far as we can go.

> THE COMMISSIONER: Ves.

THE WITNESS: That is the result that we would put into the computer.

THE COMMISSIONER: Yes. But you don't tell . them that there won't be another one.

THE WITNESS: That's correct.

THE COMMISSIONER: You see if somebody were waiting for the results of the 4.7 he might well assume that the 72 that came in a few days later was the same, was the 4.7 diluted several times.

THE WITNESS: But isn't that a different specimen?

THE COMMISSIONER: But I don't think he noticed that and I really don't think most people would. I may be wrong. I don't think most



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be 72.

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people would check the number.

THE WITNESS: Yes.

THE COMMISSIONER: No question it is a different sample, 4.7 is from the vein and 72 is from the pelvic cavity.

THE WITNESS: The greater than 4.7 is from the vein, yes, and the 72 is the questionable one.

THE COMMISSIONER: Well, I just mention it to you because if - you see, greater than 4.7 can conceivably be 4.8.

THE WITNESS: Yes.

THE COMMISSIONER: Which is not that

THE WITNESS: Sure.

THE COMMISSIONER: But it can also

THE WITNESS: Yes.

alarming. I just wondered if you knew at that time, as you would know with this one, the 4.7, that you can't go any farther, if your computer has any symbol for that to tell anybody.

THE WITNESS: We could have written any comment we liked in relation to that sample as



a comment. In fact, that didn't occur on this particular occasion. I think in my preliminary hearing testimony I may have given this result as 4.7 with insufficient to repeat.

THE COMMISSIONER: Yes.

MS. CRONK: Q. Doctor, in addition to the possibility of making a notation on the biochemistry printout report, had the level of greater than 4.7 been reported by telephone on January 12th when that level was available? Is it not possible that during the course of that reporting discussion it could have been mentioned to pathology that no further sample was left to permit a further dilution. I take it that is a possibility.

- A. It is a possibility, yes.
- Doctor, with respect to that sample that lead to the greater than 4.7 result would I be correct in assuming that at the time it was assayed you did not know the site from which the sample was taken other than the fact that it was a vein. That was the only information available to you?
- A. You mean in respect of the sample from the vein or the possibly diluted sample?



the vein.

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Q.	The	vein.	The	sample	from

- A. Yes, that's all we knew.
- Q. And did you know anything about the circumstances under which that sample had been taken, the one from the vein?
  - A. No.
- Q. All right. And similarly with respect to the sample that resulted in a level of 72, did you know at that time the site from which that sample had been taken? You will recall that there is an O, another on the digoxin entries in your digoxin books for that.
  - A. Yes.
- $\Omega$ . You had no information as to the site from which this sample was obtained?
- A. No. But I believe a sample that looked like blood had been received, so, it would be reasonable to assume that it was a blood sample as opposed to another fluid.
- Q. But I take it, Doctor, you did not have any information through that period from January 12th through to January 16th as to the circumstances under which that sample had been taken, the method used or the timing?



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A. The milking of the veins and all this kind of thing I learned about very much later.

Q. Well, I am talking about now the pelvic cavity sample as it happens.

A. Yes, sure.

And I take it you did not then have any information or knowledge as at January 16th as to the circumstances under which that sample had been taken?

A. No, I didn't.

Q. All right. And Doctor, when you learned of those two levels, the greater than 4.7 level and the level of 72 nanograms you have told me that you did not at that stage know that Janice Estrella had not received digoxin for four days prior to her death?

A. No.

Q. All right. Had you known that, Doctor, had you known from whatever source of information that that was the case, would those two numbers at that stage have caused you sufficient concern to contact the Pathology Department at that stage and enquire further into the matter?

A. That's speculation.



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			Q.	All	right.	You	don't	know
how	you	would	have	reacted	? :			

A. I mean, I hope I would have done but...

 $\Omega$ . Well, that's fair, Doctor.

Mr. Commissioner ---

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A. Can I just mention one thing as well in relation to quality of samples in general in that I was here just for Dr. Cutz' last few words of his testimony and he was indicating, you were asking him about potassium results and he was saying you can't really rely on that result the sample is hemolyzed. Okay, if anybody tells us that the sample that they are giving us is anything - that the quality of the sample is possibly compromised, then any significance that we might attach to that sample is reduced. If they tell us it is hemolyzed, if they tell us it is full of lipids, if they tell us it is contaminated with something, we immediately detune if you like in terms of our sensitivity to the results that we finally obtain on that sample.

Q. I understand, Doctor. And in this case, although you don't know who provided that information, when or how, it is clear that the technologist who conducted these assays had been



informed there was an issue about at least the one sample, the pelvic cavity sample, correct?

A. Yes.

 $\Omega$ . All right. But there was no such indication with respect to the leg vein sample?

A. That's correct.

 $\Omega$ . All right.

Mr. Commissioner, may we take our

break now?

THE COMMISSIONER: Yes, all right, we will take 15 minutes.

---Short recess.

--- Upon resuming.

THE COMMISSIONER: Ms. Cronk, this document that has January 13th and January 14th on it, should it be added to one or the other of these two?

MS. CRONK: I neglected to ask you to add it in. It should be properly attached to Tab 45, Exhibit 32B. It is the first page of that book.

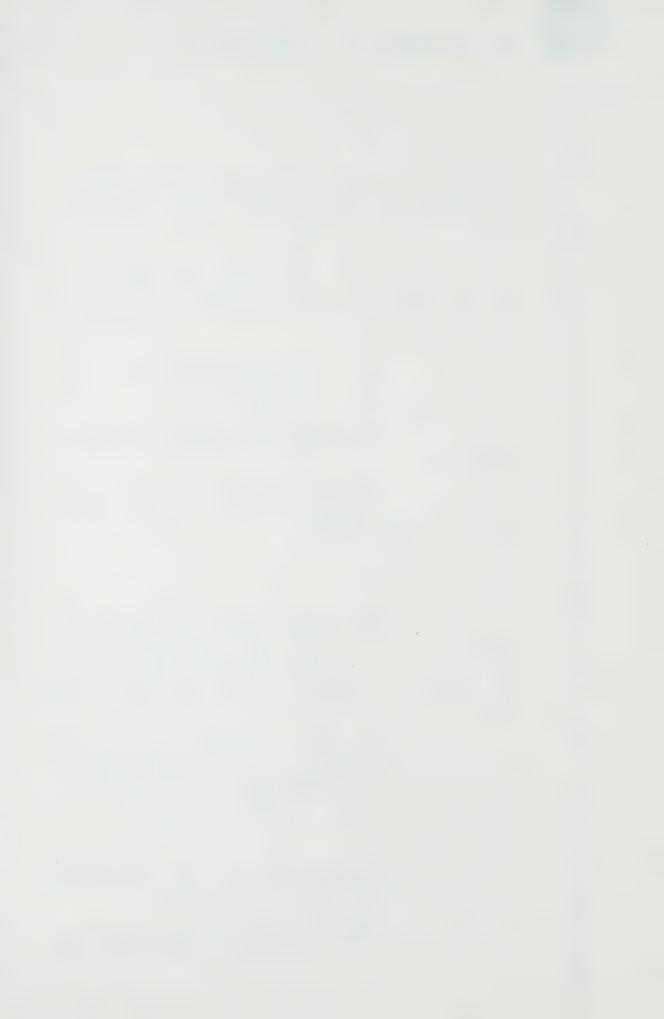
THE COMMISSIONER: Yes, all right.

MS. CRONK: 45A, sir?

THE COMMISSIONER: Well, it is part

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of Tab 45 of Exhibit 32B, all right, we will mark that accordingly.

---EXHIBIT NO. 32B, Tab 45: Two pages, January 13th and January 14th.

THE COMMISSIONER: I guess everybody will have to have a copy of that.

MS. CRONK: They do, sir, they have been distributed.

THE COMMISSIONER: Oh, have they, all right.

MS. CRONK: Q. Doctor, two final points with respect to Janice Estrella. You mentioned before the break your reaction and that of the technicians in your biochemistry laboratory if some indication was given to you that a particular sample had been hemolyzed or was otherwise in question as to its quality. Do you recallthat?

A. Yes.

Q. What do you understand a hemolyzed sample to be, Doctor?

A. One containing hemoglobin from the red cells possibly due to red cell breakdown during the collection of the sample, physiologically or during the preparation of the serum sample from the whole blood.



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			Q.		All	right	t	And	what	effect
if	any	would	that	have	in	your	vie	W OI	n the	quality
of	the	sample	e for	the	purp	poses	of	a di	igoxir	n assay?

A. I think that that particular assay is relatively insensitive to hemolysis.

We have analyzed quite a number of samples that were hemolyzed before and we have not obtained unexpected results directly associated with them.

O. So, I take it then it is in respect of assays for other drugs, for example, potassium?

A. Yes.

 $\Omega$ . Drugs of that kind that a hemolyzed sample would be of concern?

A. Yes.

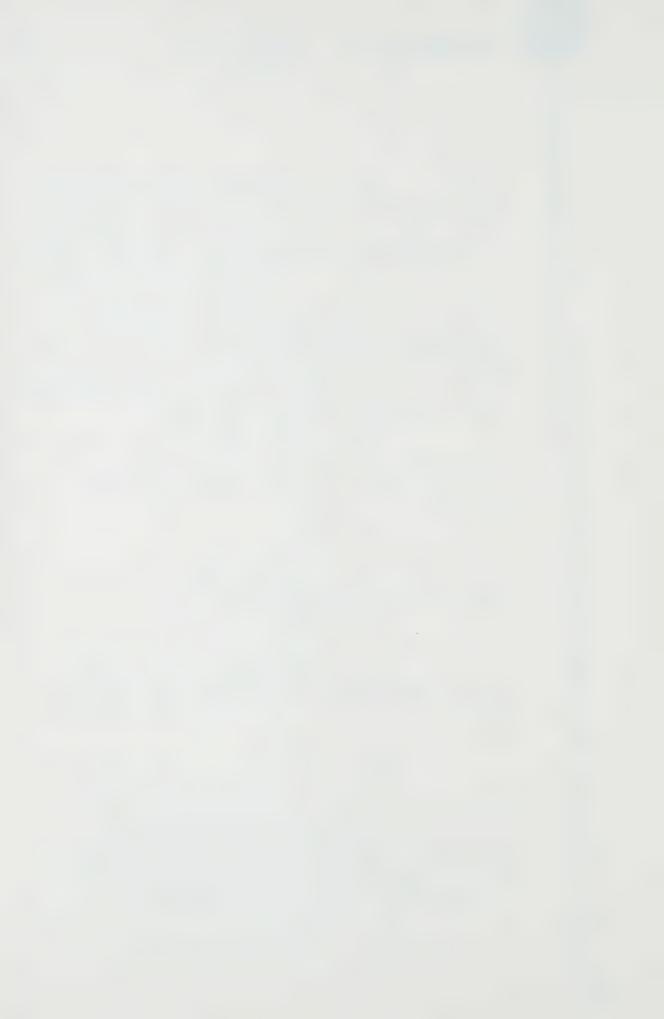
Ω. All right. But it is not in your experience of concern with respect to digoxin assays?

A. No.

Q. All right. Doctor, as well, we have discussed what was in your mind, as I understand it, when you learned of the postmortem level on Janice Estrella of 72 nanograms?

A. Yes.

Q. What was in your mind as



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possible explanations for that level and you have told me first of the possible explanation that there had been some error analytically in the assay or the performance of the assay and you satisfied yourself that that was not the case. Do I have that correctly?

A. Yes.

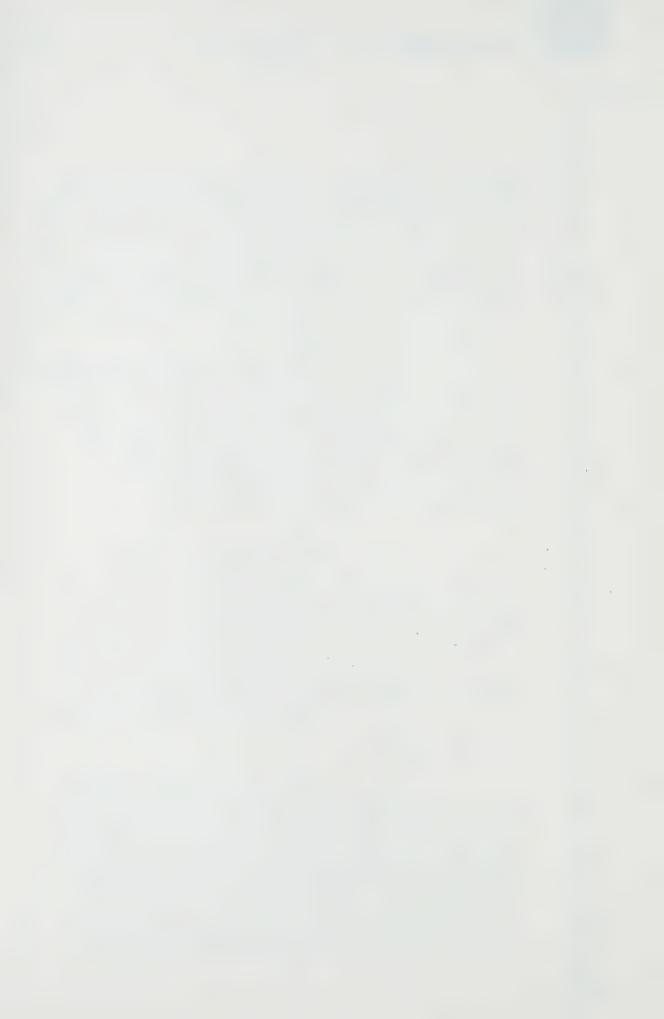
Q. All right. And you have told me as well that it occurred to you that the sample might have been taken too soon in time from the time when the last dose of digoxin had been administered and we have discussed that?

A. Yes.

Q. Was there in your mind at the time, Doctor, any other possible explanation for why this level of 72 nanograms might have resulted in the case of Janice Estrella other than those two explanations you have already offered?

A. Difficult as it may seem now, no, there wasn't.

Q. Thank you, Doctor. Doctor, we have heard from other witnesses that when they learned of the level of 72 nanograms with respect to that sample for Janice Estrella that amongst other matters at least some of those individuals assumed or thought that one possible explanation



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might have been a decimal error in the level that had been reported. Were you at the time satisfied that the mathematical calculations and the technical calculations that are performed on the gamma counter in the immunoassay test had been achieved correctly without error?

A. Yes.

Q. All right. Was that a matter which you specifically addressed at the time?

A. In relation to decimal point?

Ω. Yes.

A. No, in that the whole analysis had taken several days and everything was pointing to a higher result.

Q. Right.

A. So, there was no question that it was 7.2 as opposed to 72.

Q. All right. It was clear that the level was 72?

A. Yes.

Q. Given that there had been, as we have seen, several dilutions of that sample before that result was achieved?

A. That was my interpretation of these observations.



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- $\Omega$ . And is that your understanding today of that level?
  - A. Yes.
- Q. Thank you. Doctor, may we turn then to the case of Kevin Pacsai. The evidence with respect to that child has been that he died in the Hospital for Sick Children on March 12th, 1981 and as well that a number of digoxin assays both during his life and on a postmortem basis were carried out in the biochemistry laboratories. Can you tell me, Doctor, were those assays conducted under yoursupervision?
  - A. Those assays for digoxin?
  - Q. On Kevin Pacsai.
  - A. For digoxin?
  - Q. Yes.
  - A. Yes.
- Q. All right. Would you turn,
  Doctor, if you would please to Tab 45 again of
  Exhibit 32B.
  - A. Yes.
- Q. It is Tab 45, Doctor, page 23 if you would please. I'm looking, Doctor, at the entries for the results of digoxin assays conducted on March 13, 1981 which are set out in the bottom



half of page 23. Do you see those entries?

A. Yes.

Q. All right. Doctor, I'm referring to items numbered 4 and 5 amongst those entries related to Kevin Pacsai and specifically if I'm reading those entries correctly, and I would ask you to tell me if I am not, it appears that as a sample taken on March 12th, 1981 was assigned Sample No. H88043, that it came from the ICU and that it was assayed with the result of greater than 10 nanograms. Do you see that initial entry, Doctor?

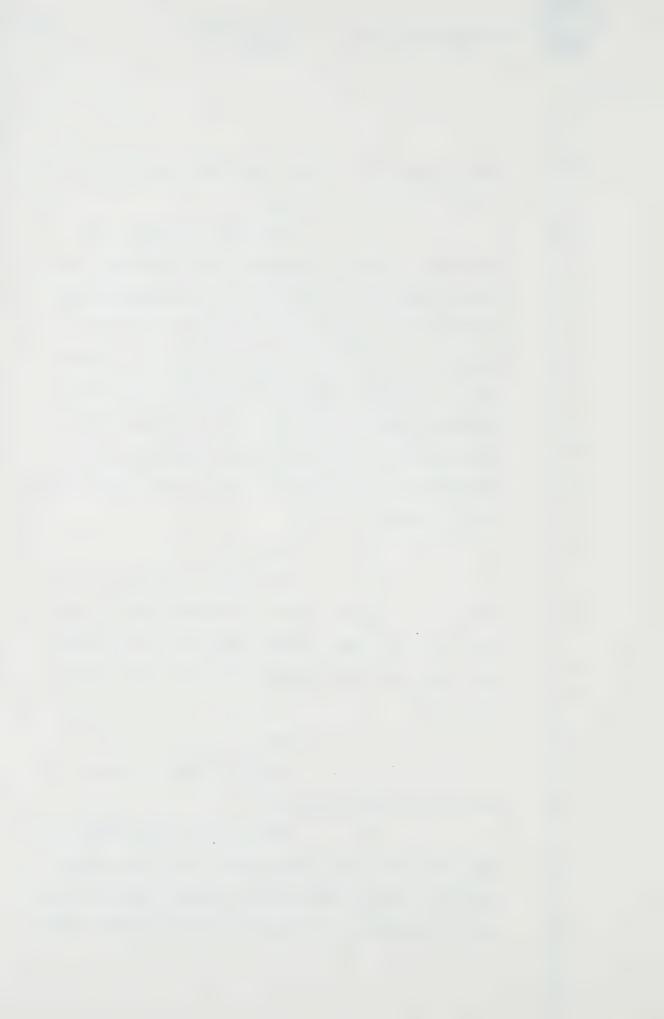
A. Yes.

 $\Omega$ . All right. And immediately below that, Doctor, there is another entry also related to the same number taken on the same day and then these words appear CMT, NS $\Omega$  for further dilution.

A. Yes.

 $\Omega$ . Could you tell me please what those words refer to?

A. CMT is short for comment, it indicates that the person who is to enter these results into the laboratory computer should enter in the location for comments. The following comment



NSQ for further dilution.

Q. All right. I take it then that with respect to that particular sample after the first assay had been done there was no further sample, or at least insufficient sample available for further dilution and analysis, is that correct?

A. After the...

Q. After the first assay had been done there was then insufficient sample available for further dilutions and for further assays, is that correct?

A. Yes. In fact, there was very, very little of this sample available. You will note on the left hand side it says one tube and then it says one tube times two.

Q. All right.

A. So, there was 50 microlitres available to put into one tube and there was presumably 25 microlitres or a very little amount to put into the next tube. Otherwise, the technologist would have done everything in duplicate, which is the usual way.

Q. I see, Doctor. Doctor, referring to that first reference to one tube, immediately below that we see a number which appears



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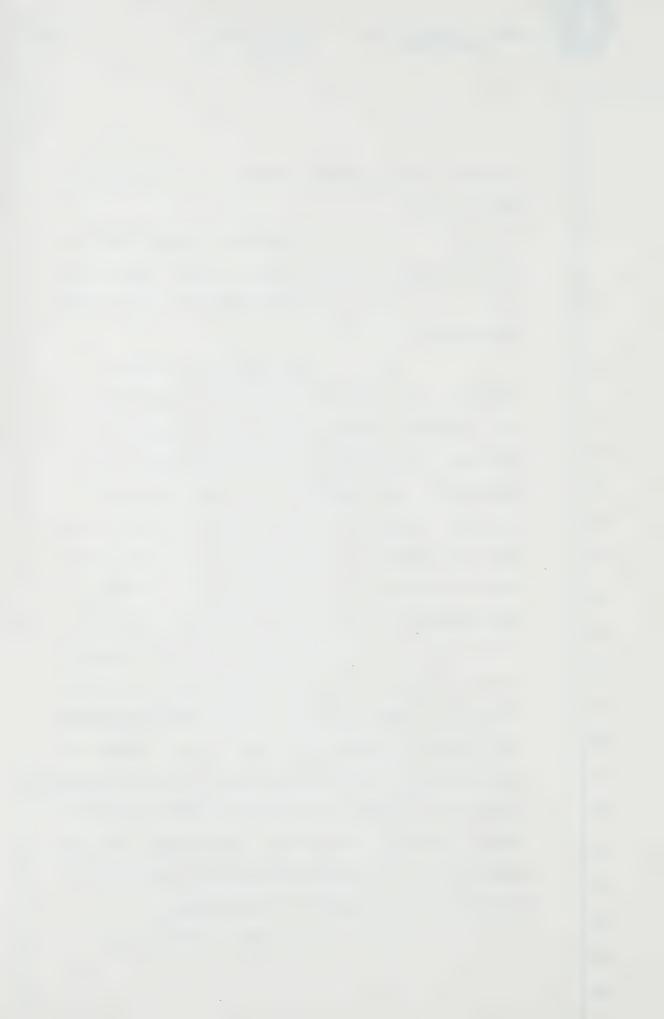
to be 16. It is either 160 or 116.0. Do you know which it is?

A. It looks as though there is a decimal point directly on the line, doesn't it.

Q. Do you know what that refers to, Doctor?

Not unless the computer Α. printout - the computer will give a number even if that number is greater than 4.7 or greater than top standard. That number is unreliable and it is produced by the computer, by an extrapolation process. On occasion we will note the actual number that was obtained by the computer printout on the computer printout by the computer as an aside; in other words, we would report a greater than 4.7, let us say, but if the computer printout happened our own internal section printout said 5.3 or 5.4 we may note that somewhere in our book and perhaps the computer produced the result of 16. Above the high standard, this has relatively little reliability and that we wouldn't report that number, but it is useful internally to know how much higher than that number it is. My guess would be that the 16 is a number that is produced by the computer.

Q. All right. And in that



regard, Doctor, I take it that you would not be satisifed that the actual level over 10 was 16?

A. No.

Q. That number is unreliable?

A. No.

Q. All right.

A. And in fact the over 10 which appears to be associated with the first analysis is in fact the result of the two analyses together.

That was the report that we produced on the basis of those two analyses, the single tube and the times 2 tube.

All right. Well, you are anticipating me, Doctor, because I was going to then ask you what the meaning of the entry on the second reference to one tube was because we see encircled the numbers times 2 and I took that to mean that the sample when it originally arrived was assayed neat and then was assayed times 2 and it was a result of that dilution that the level of greater than 10 was achieved. Do I have that correctly?

A. Yes, except that these were done simultaneously.

Q. I see. So, it was in respect of the second tube, it was the second tube of



tubes.

specimen that was diluted times 2.

A. Second tube. I'm sorry, are you saying that there are two sample tubes coming in or are you talking about two analytical tubes?

Q. I'm talking about two analytical

A. Okay.

Q. The question probably to you, Doctor, is was this sample in part assayed neat and then in part assayed on a diluted basis of times 2?

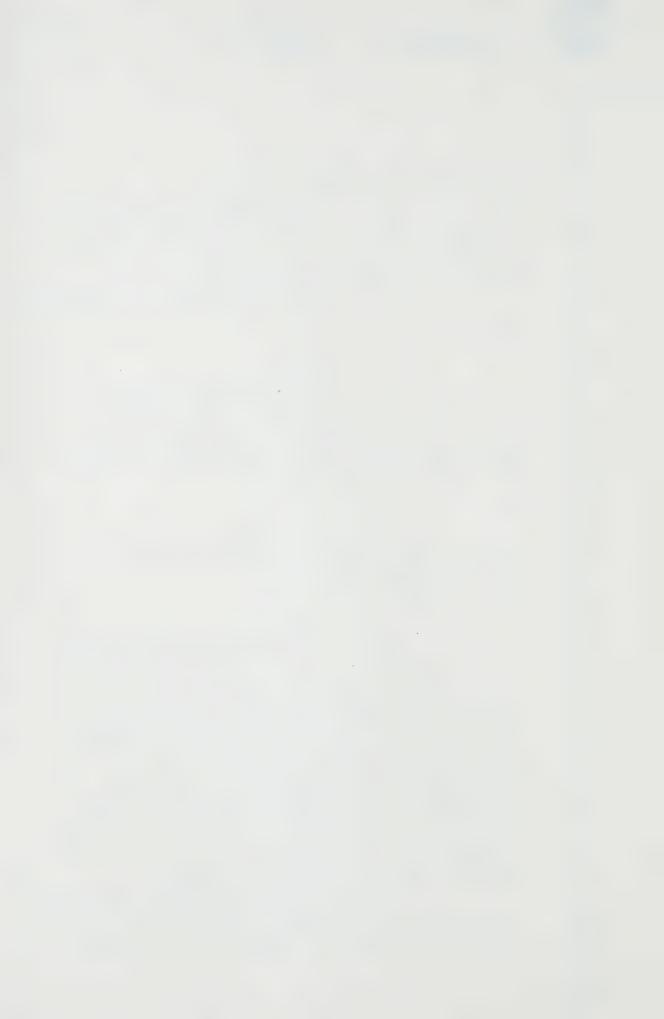
A. Yes.

Q. All right. And was it as a result of that dilution assay that resulted in a level of greater than 10?

A. Yes.

Q. All right. And with respect to that level once again, Doctor, we see that the first and the second entry refer to the ICU. In light of what you have explained to us previously is the proper interpretation to be placed on information in that column, I take it that the request for the assay came to the biochemistry lab from the ICU. Do I have that correctly?

Well, to assist you, Doctor, and there is one other matter and then perhaps we can look at



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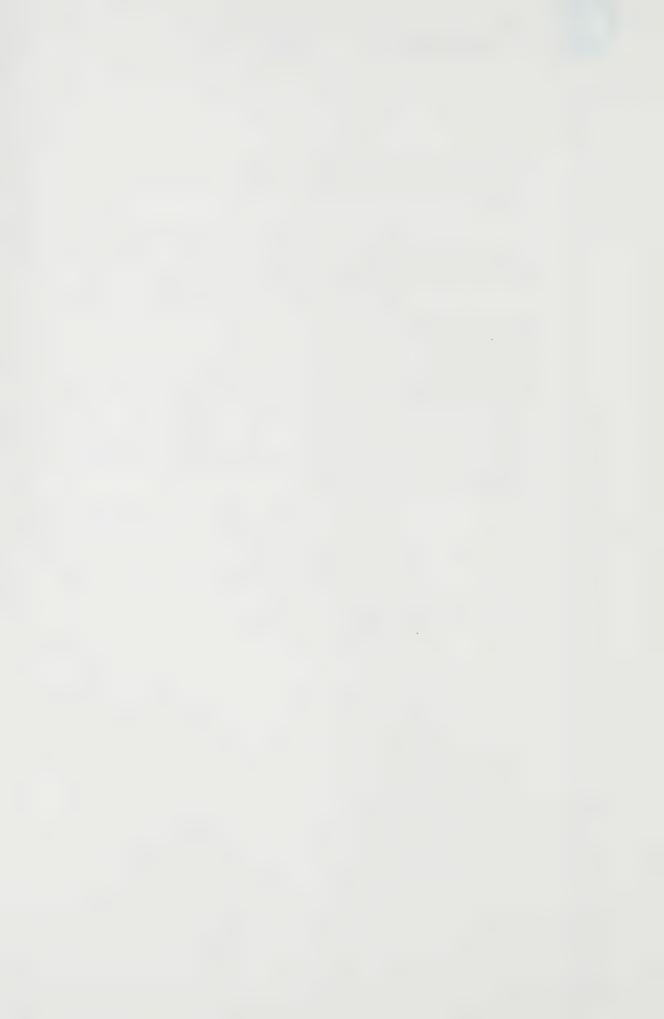
the requisition form and that may assist you, all right?

A. You are implying that the patient was on the ICU when the sample was taken.

Q. No, I wasn't suggesting that.

As I understand it that is in fact the evidence
to date, but as I understand what you have said about
the information contained in that column, when you
insert a ward, a specific ward, in this case the ICU,
that means that they were the originator of the
request for the assay?

- A. Under normal circumstances, yes.
- Q. All right.
- A. But in fact this wasn't the case with this particular sample.



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sample, yes.

			Q .	A11	right.	And	where	did
you	understand	the	request	came	e from?			

A. Well, my understanding that came to some extent later was that Dr. Costigan himself had brought the sample.

Q. And do you know where the child was when he drew that sample?

A. Where the child was? I believe the child was in the ICU at the time.

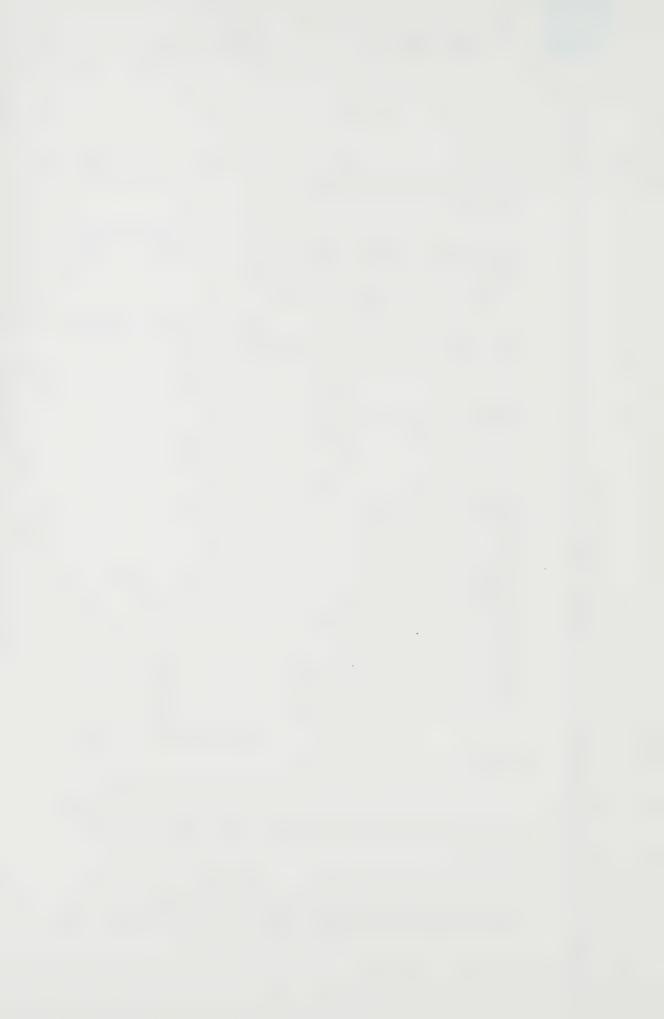
Q. Thank you, doctor.

And, doctor, under the time column of information you see the number 2100 hours. Now in accordance with your evidence as to how the information in that column is normally to be interpreted, one would usually take that to mean that the sample was collected at 2100 hours on the 12th of March. That would be the interpretation in accordance with the normal rules; is that correct?

A. If this were a normal

Q. Was there something about this sample of and in itself that was unusual, doctor?

A. Yes. Firstly I don't know whether that 2100 hours -- I believe that 2100



EE2

hours has been put in later because there is a vertical dash down which suggests that we didn't know the time at the time we were doing the analysis on the 13th of March.

It is also my understanding that this particular sample was a very unusual sample.

As I mentioned, Dr. Costigan, it is my understanding, brought it in, and that this sample had spent some time in Hematology.

Q. And would that somehow influence the entry at the time in the book, doctor?

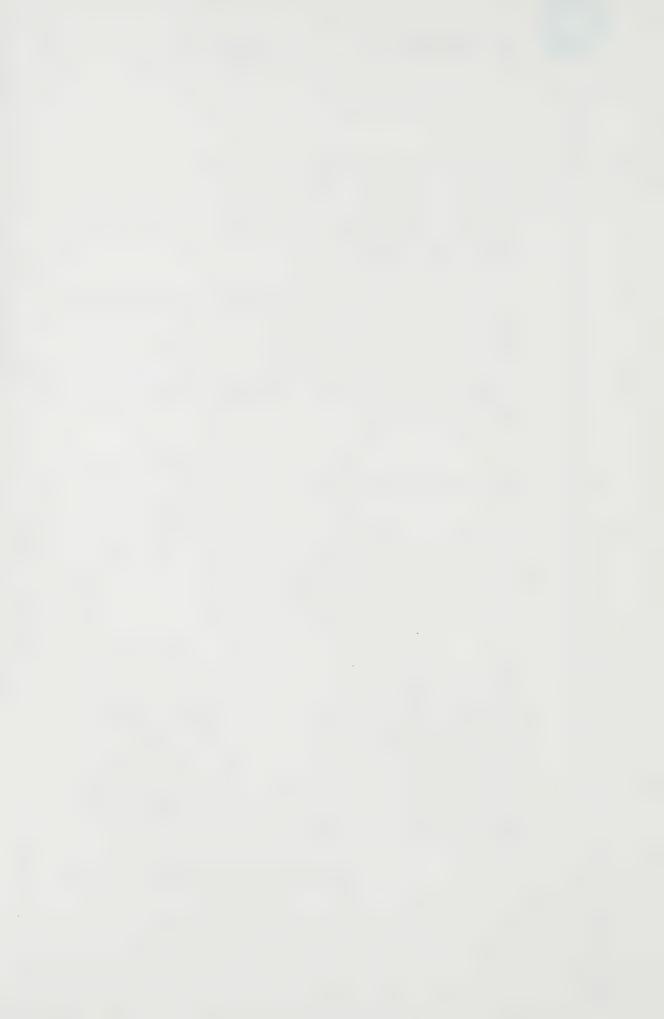
A. Yes, because I think on the basis of the information that we had right at the instance of doing the analysis we didn't have that particular specimen time noted.

Q. Right. To assist you in that regard, doctor, the clinical chemistry requisition form which applies to this sample, found at Tab 55 of the same book that you are looking at, indicates that the sample was taken on March 12th, and no time, or at least no hours indicated as to when the sample was taken.

Would you turn to Tab 55, please.

A. Yes.

Q. Do you have it?



Ellis dr.ex. (Cronk)

A. Yes.

Q. There is, however, a date stamped there that appears upside down, at least on my copy, and it is March 12, 1944 hours. Do you see that?

A. Yes.

Q. Am I correct, doctor, that the date stamp of that kind when it appears on these requisition forms is a date stamp attached or affixed to the requisition forms once the form is received in the Biochemistry Department?

A. It is printed, yes, by a time clock.

Q. And the purpose of doing that is to indicate when the sample is received in Biochemistry?

A. Yes.

Q. So in this case it would appear that the sample was received on March 12 at  $7:44~\mathrm{p.m}$ .

A. That is correct.

Q. All right, doctor.

Doctor, as you indicated it was your understanding that the sample had been obtained by Dr. Costigan, as I understood it, while the child



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was in the ICU. That is when the sample had been obtained.

When this assay was being conducted on March 13th, did you have any understanding then as to whether the sample was an ante mortem or post mortem sample?

- A. On the 13th of March?
- Q. Yes.
- A. I had no reason to believe this was a post mortem sample.
- Q. Did you assume that it was an ante mortem sample?

A. Dr. Costigan was I think in the lab or communicated to the lab -- we just couldn't quite explain how a sample that had been received on this particular day -- I think the time of receipt in the Biochemistry Lab follows the time of the child's death.

- Q. That is correct, doctor.
- A. So we really couldn't explain whether this was really a post mortem or an ante mortem sample.
  - Q.. At the time?
  - A. At the time, yes.
  - Q. Doctor, do you recall how



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this sample arrived in the Biochemistry Lab?

A. I personally don't recall how it arrived, but we tried to piece together information afterwards and spoke to various people, and it is my understanding, as I say, that Dr. Costigan was concerned when the child died, whenever the child died; he was concerned that the child had died and he attempted to, because of the clinical condition of the patient and the symptoms that the child was showing before death, he became concerned about the possibility of digoxin toxicity, so that he had or he had instituted the taking of several blood samples.

or if my understanding of the evidence is correct he had initiated the taking of several blood samples, one of which I think was for hematology requests, and the other which was for electrolytes at the time the child was ill in the Intensive Care Unit.

It is our policy in Biochemistry to discard any sample remaining at the end of the shift, at the end of the technology shift, for routine tests.

In other words, if something comes in for potassium or something comes in for



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gases, any leftover sample will be discarded unless something else has been requested that hasn't been analyzed. Okay.

So I think when he then thought about digoxin toxicity he tried to look out the sample that he had sent to Biochemistry, if my understanding is correct, but wasn't successful because the sample that we had had had been thrown away.

- Q. May I stop you there for a moment, doctor.
  - A. Yes.
- Q. To the best of your understanding was the sample that was actually assayed that resulted in this level for digoxin brought to the lab by Dr. Costigan?
  - A. Yes.
- Q. Doctor, to assist you with respect to the events of how that sample arrived in Biochemistry and the events following the assay, it is my understanding the technologist involved in the conduct of the assay kept notes of those events.
- A. No, she pieced together notes fairly shortly after the further deaths.



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doctor	, ha	andw	ritten	note	s dat	ed a	round	l March	1 2	24,
1981.	It	is	indica	ted	that	they	are	"Mary	s	notes"

Can you identify those notes for me and, if so, who is the author of them?

A. Yes. It is my recollection that these notes were prepared by Mary Allin,

- Q. I'm sorry, Mary Allin?
- A. Allin, yes.
- Q. And who is Mary Allin?
- A. She was one of the

technologists.

A-1-1-i-n.

- Q. In your lab?
- A. In my lab.
- Q. All right. Was she

involved in the conduct of this assay on this sample of Kevin Pacsai?

A. No, she wasn't in respect of this particular one.

Q. All right.

I would ask, sir, that those

notes be marked as the next exhibit.

THE COMMISSIONER: Yes, I guess

so.



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MS. CRONK: Q. Doctor, I take it these notes were brought to you by Miss Allin?

> Α. Yes.

0. All right. Do you

recognize her handwriting?

Α. I believe it to be hers. THE COMMISSIONER: What number?

THE REGISTRAR: 209.

--- EXHIBIT NO. 209: 2-page document entitled "Mary's Notes, around 24

March '81".

MS. CRONK: Q. Doctor, with reference to the first paragraph of the note, it

> "Peter came into the lab to query a digoxin level on..." THE COMMISSIONER: Just a moment,

please.

reads:

MR. ROLAND: Mr. Commissioner, I haven't objected to the introduction of the notes, but I take it it is clear these are not contemporaneous notes.

THE COMMISSIONER: No.

MR. ROLAND: By Mary Allin after

the event.

THE COMMISSIONER: Even if they



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were contemporaneous they wouldn't be admissible in any proper court of law which this is not.

THE COMMISSIONER: That would be of assistance to him but the only reason we can accept them is because we are a Commission.

MR. ROLAND: Exactly.

THE COMMISSIONER: We are not a court and we can receive anything. Even if it comes in by carrier pigeon or something we can take it for what it is worth.

MR. ROLAND: That may very well happen in this inquiry.

THE COMMISSIONER: Yes.

MR. ROLAND: All I want to say is that because they are not made contemporaneous to the event they should be regarded as far as accuracy is concerned with that in mind.

THE COMMISSIONER: Yes. I agree with everything you have said but still you are



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not objecting and I guess by our rules they are clearly admissible.

All right.



EMT.jc EE3. 

Q Doctor, with respect to the first paragraph of the notes as I understand the entry it reads as follows:

"Friday morning. Peter came into
the lab to query a digoxin level on
Kevin Pacsai. Apparently the blood
arrived Thursday evening yet the baby
had died Thursday morning. I looked
up the requisition, the serum
(hemolyzed) was separated and frozen
and requested for digoxin only. There
was no sample time on the requisition.
Peter explained that there was a
query over ... "

I take that to be potassium?

A. Yes, K-plus.

Q. "... or digoxin toxicity. So on setting up ...

The digoxins?

A. Yes.

Q. "... the serum was done straight and on a X2 dilution, anticipating possible high digoxin. The result was greater than 10 on X2 dilution but we figured the sample



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"must have been taken shortly after the digoxin had been given to the patient as we didn't have dose and sample times."

Stopping there for a moment, Doctor, I take it you have seen these notes before?

A. Yes.

Did Mary Allin at any point describe to you the events of the Thursday evening? That is the arrival of the sample and the Biochemistry lab for assay?

- She would not have been present.
- All right. Do you know who

Miss Allin is referring to as Peter?

- That would be Peter Huggard. A.
- Q. All right.
- A. Huggard, H-u-q-q-a-r-d.
- Q. And what is his position, Doctor?
- Α. His position is chief

technologist.

- Q. In the Biochemistry lab?
- A. Yes.
- Q. And with respect to this particular sample, Doctor, was it suggested to you following the conduct of the assay on the sample by

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any of the involved technologists that the sample may have been taken shortly after the digoxin had been given to the patient?

No, I don't think so. In fact on that requisition I believe Dr. Costigan wrote "dig. toxicity question mark" if my recollection of the requisition is correct.

Thank you. Apart from whatever Dr. Costigan wrote on the requisition form, do you have any recollection of the technologists who were involved in performing the assay raising with you the suggestion that the greater than 10 level might be explained by virtue of the fact or the suggestion that the sample had been taken in close proximity to the time at which the last digoxin dose had been given.

Α. Just taking the results as they stood that was one possibility.

Do you recall whether or not that was specifically raised with you by the technologist; who conducted the assay?

I think we later - I think we learned the following week, early in the following week that the last sample, the last digoxin dose had been given the previous night, prior to taking the blood sample.



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0. Well, Doctor, I would like to direct your attention to March 13th, the day this assay was conducted as opposed to anything that may have happened the following week.

On that day when the assay was conducted do you recall one way or another whether or not, first of all, the level of greater than 10 was brought to your attention? Were you made aware of that on the 13th of March?

Yes, I think I was, yes.

Q. And when you were made aware of that level did any of the technologists who had been involved in performing the assay as best you can now recall it suggest to you or raise with you a possible explanation for that level, mainly that the sample had been taken too soon after the last dose of digoxin had been given?

Was that a matter discussed on March 13th as best you can recall?

This is something that we always A. consider because-as our first explanation for something unless there is a positive indication to the contrary.

> All right. Q.

Because over the course of the previous few years that had been the most common reason



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why we had got unusual digoxin results. You know, you go down to the ICU and you find out that the sample, they have got a new nurse on and the nurse didn't really know the procedure. She remembered that she should take a digoxin sample - not in respect of this case but I am saying in the general case you usually find that somebody wasn't quite sure and they took a digoxin result at the inappropriate time, one hour, two hours, half an hour after getting the dose.

Q. So I take it then, Doctor, that given your general experience in the past with digoxin assay results that appeared to be elevated or irregular, the possibility of that happening was something that would have been in your mind on the 13th of March?

A. Very much so, yes.

Q. And, Doctor, given that Miss
Allin's notes indicate that the sample at issue
resulted in a level greater than 10 on a dilution times
two, I take it you would have no difficulty in
accepting that her notes refer to the sample numbered
H88043 that we have been discussing in the digoxin
book?

A. Yes.

And if we could turn then to the



second passage of the notes:

"Monday morning. First thing
(before 8:30 probably) phone call
requesting Friday's digoxin results
on Kevin Pacsai."

A. Yes.

Q. "I explained that there was a query about this sample and I asked if he knew about this. He said yes he knew all about it, that he had brought the sample to the lab himself Thursday evening - that he had dug it up from ..."

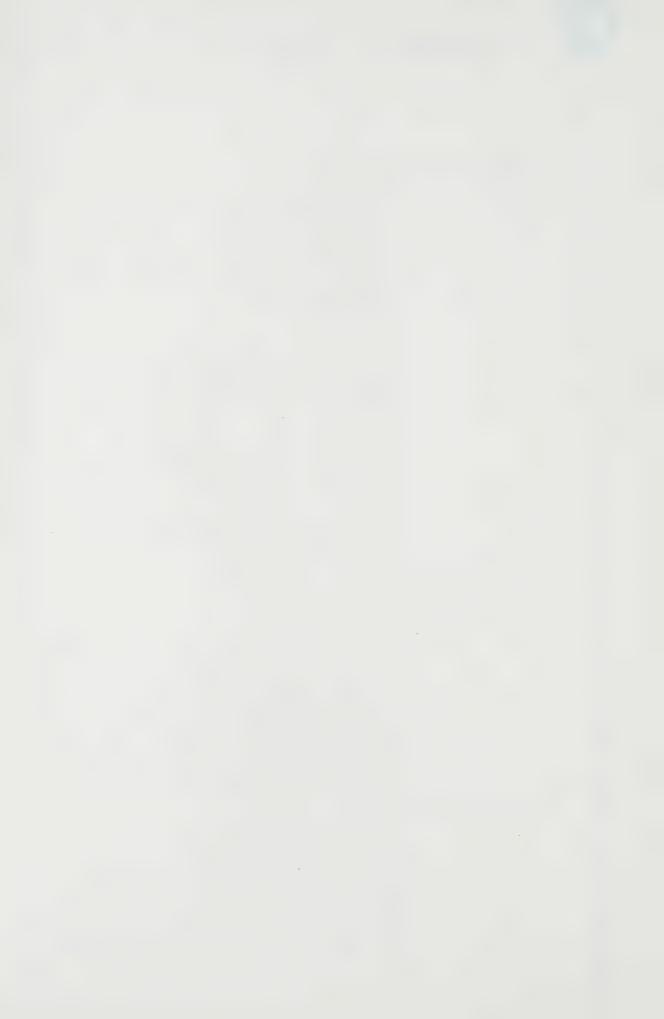
I take it Haemotology?

A. Yes.

Q. "I asked what time sample drawn. He said Thursday morning. I asked when the patient had received his last dose before the sample was drawn. He said 9.00 p.m. Wednesday evening."

Going to the next page:

"I was surprised. I explained: well the dig. result was high, greater than 10 on dilution so it looks like dig. toxicity. We didn't have enough



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"He asked if our dig. assay was reliable when done on a haemotology sample which contains EDTA. I didn't know if this would affect our assay

so I passed the call on to Dr. Ellis."

"serum to do a greater dilution.

Do you recall, Dr. Ellis, having a

phone call passed on to you on Monday, that would be March 16th, by Mary Allin?

> A. I personally don't, no.

Do you have any understanding or knowledge as to who the person was who made the phone call that Miss Allin is referring to in this portion of her notes?

Discussing it later on the following week I believe this person is Dr. Costigan.

All right. I take it then, Doctor, perhaps you are in a position to tell me did Miss Allin draw to your attention, the nature of the discussion that she had had with Dr. Costigan concerning the timing of the last dose of digoxin and the timing at which the sample was drawn? Was that a matter that you discussed after the 13th of March with Miss Allin?

> A. I am not quite sure with



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Miss Allin particularly, but also with the doctors who were concerned, who were involved, with Dr. Costigan particularly.

Q. Did you speak to Dr. Costigan personally about that?

A. Well, all aspects of this, yes. He was concerned about the case and so there were various conversations that took place.

All right. Doctor, you have Q. told me you don't recall specifically whether or not Miss Allin passed along a phone call to you?

A. No.

Q. And Dr. Costigan on Monday,

March 16th?

A. No.

Do you recall one way or another?

A. I don't, no, but I have seen these notes several times since that time.

Q. Do you have any reason to disagree with the notes?

A. Oh, no, no. I think it could well have happened. I just don't remember every single phone call that I make.

Q. I understand.

Then with respect to the discussion



concerning the time at which the sample had been obtained, was there in your mind on March 16th any further issues as to whether or not that sample had been drawn at an inappropriate time?

A. I am sorry, on March 16th?

Q. On Monday, March 16th, was there any further issue in your mind as to whether that sample had been drawn at an inappropriate time?

A. This particular sample was not of too much concern to us in that we had additional materials that we hadn't yet analyzed, okay, so there were some samples dated 13th of March, autopsy samples that were actually analyzed the following Monday, March 16th. And so we are dealing there with a result in front of us but also some unknown question marks behind it. You know, some samples had already arrived.

Q. I will be coming to the post-mortem samples in a moment, Doctor.

A. Okay.

Q. But just dealing with this sample that Dr. Costigan apparently brought to the Biochemistry laboratory on the evening, on Wednesday evening, you have told us that because of your general and prior experience with respect to digoxin assays --



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A. Was it Thursday evening or

Wednesday evening according to 0. the notes. Oh, I am sorry. It was Thursday evening, it was the last dose that was given on Wednesday. You are quite right, Doctor, I am sorry.

You have told us because of your prior experience with digoxin assays the possibility of an erroneous level resulting because a sample was taken too soon after the last dose was a matter that was very much in your mind on March 13th?

> A. Yes.

All right. Do I understand Q. that correctly?

> A. Yes.

So that was I take it an unresolved issue in your mind at that time with respect to the sample?

> A. Yes.

That was a possible explanation for the sample?

> Yes. A.

Then comes the Monday, March 0. 16th. My question of you, Doctor, is by that time, on the 16th of March, did you then have any further or



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lingering	question	in your	mind	as to	whether	or	not
this part:	icular sam	mple had	been	drawn	at an		
inappropri	iate time?	?					

A. No. Well, I had no reason to believe that it had been drawn at an inappropriate time.

Q. Well, on the basis of your discussions with Dr. Costigan do you recall discussing personally with him the time at which the last dose of digoxin had been administered and the time at which the sample had been taken?

A. We came to know that at some time during that week.

Q. And when --

A. I suspect - you know, it could have been the Friday; it could have been the Monday. I think it was probably the Monday.

Q. And, Doctor, when you did come to know that, would I be correct then in understanding your evidence to be that you would no longer regard that possibility as a likely explanation for this level?

A. Yes.

Q. Doctor, on page 2 of Miss
Allin's notes we see reference to a haemotology sample
containing EDTA. Can you tell us what that refers to?



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acetic	acid	and	it	is	used	as	a	preserv	vative	for	-	
haemoto	logy	samp	ples	5.								

Do you recall discussing with Dr. Costigan the possible implications of EDTA being contained in a blood sample used for digoxin assay?

A. If a sample is unusual in respect to the usual method of preservation, then we would obviously be concerned about that.

I am sorry, Doctor, that really wasn't my question. My question was do you recall discussing with Dr. Costigan the possible implications of EDTA being contained in a blood specimen sent for digoxin assay?

Not with him specifically on that particular date.

Do you recall that issue being

A. Yes.

In the context of this sample on Kevin Pacsai?

> Yes. Right. A.

And as a result of that issue 0.

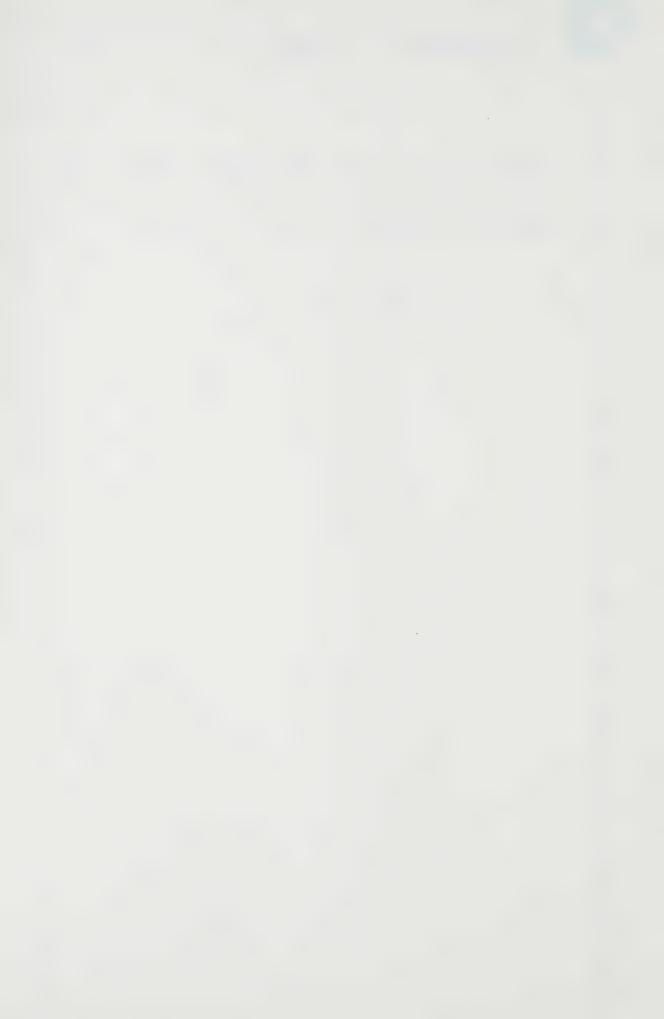
being raised --

raised?

Sorry. I recall it being raised A.



because - well, I recall this question coming up, and in fact on March 17th that we did various things in EDTA to see whether it made any difference.



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				Q.	We	ell,	tha	at w	as m	y ne	ext	quest	cior
of	you,	Doc	ctor.	Car	n we	tur	n it	E yo	u wo	uld	to	page	25
of	Tab 4	45,	Exhib	it :	32B,	do	you	hav	e th	at?			

A. Yes.

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Doctor, I take it you just told 0. me that on March the 17th you did run tests to look into this issue of the possible effect of EDTA?

Yes, very preliminary kind of tests.

Q. Before you ran those tests, I ask you to address your mind to the situation before you ran those tests. Did you then have any opinion based on your experience as to whether EDTA contained in a blood specimen could result in an artificial or an unreliable digoxin level?

I would not have thought it likely that EDTA would have interfered with this particular assay, but I couldn't exclude the possibility that it might prior to doing these couple of experiments.

Q. And Doctor, what then did you do on March 17th to explore the matter further?

A. On March 17th basically we took a controlled specimen and we put it into an EDTA tube and we analyzed it, and this is No. 19 down the lefthand side of the page on March the 17th.





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Q.	Cor	ntro	01	А	 EDTA?
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Control A - EDTA, 1.1. Control A in that particular run had been 1.3, Item 1 on the top of that particular page.

So that the discrepancy between the normal control used on the assay and the controlled EDTA sample was a variation only of the difference between 1.1 and 1.3?

Yes, our control had not gone above 10 or 8 or 5.

THE COMMISSIONER: I am sorry, I haven't seen this yet. I see at the bottom March 17th, there is Control A and EDTA A?

THE WITNESS: Yes.

THE COMMISSIONER: And there is

something K?

THE WITNESS: This is Item 19, Tube 19.

THE COMMISSIONER: Yes.

THE WITNESS: If you look right back

THE COMMISSIONER: Yes, 1.3 and 1.1.

THE WITNESS: Yes.

MS. CRONK: Q. I take it then, Doctor,

the only differential was .2?

A. Yes.

to the beginning, Control A, Item 1.





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	Q.	Between	the	readings	on	those
ples?						

A. Yes. In addition there is a patient sample, Item No. 7, Allard, K., 0.8. THE COMMISSIONER: Oh, yes.

THE WITNESS: Item No. 7, but Item No. 18, Allard, K., EDTA 0.7.

MS. CRONK: Q. So the discrepancy in that case was .1?

A. Yes, on the basis of these two samples we assumed there would not be a difference.

Q. Was it your conclusion on the basis of those two samples that EDTA would not result in an irregular or false digoxin level reading?

A. Yes.

Q. Doctor, just in summation, and I am conscious of the time, Mr. Commissioner.

MR. COMMISSIONER: No, no.

MS. CRONK: Q. I take it, as at March 17th you had ruled out as a possible explanation for the level of greater than 10 the possibility that the sample itself had been taken too close in time to the time of the last digoxin administration, that had been ruled out, is that correct?

A. I think that was the case, yes.



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	Q.	And you	had also	by virt	ue of
the tests	run by you	on March	17th, ru	led out,	or at
least elim	inated the	possibil	ity that	the EDTA	present
in the samp	ple could h	nave resul	lted in a	n irregu	lar or
unreliable	level, do	I have the	nat corre	ctly?	

Could result in gross differences whereby a very low value or a normal value becomes greater than 10.

You have ruled out the possibility that the EDTA could have resulted in a falsely elevated level?

To our reasonable satisfaction, Α.

All right. But in addition to that by March the 17th we also received some autopsy samples and analyzed them on the same patient, and these samples had not been collected in EDTA. So whether EDTA interfered or not was less relevant, you know, after March 17th?

I see, Doctor, thank you. Other than those two possible explanations, or those two factors which you took into consideration, was there then, dealing strictly with this sample that came from Dr. Costigan, was there then anything else that presented itself to your mind as a possible explanation





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for this level of greater than 10?

A. No, because in conversations that took place at or around this time - well, each sample requisition had queried dig. toxicity. Also I think Dr. Costigan had mentioned that in his opinion this child should not have died.

Now, whether that occurred on the Monday, Tuesday or Wednesday I don't know, some time during this week that in his opinion this child should not have died.

0. Doctor, in addition to any discussion or any expression of opinion that Dr. Costigan might have made with respect to the child's death, did you on March 17th, have any remaining concern as to the validity of this level?

> A. No, not on March 17th.

Thank you, Doctor. May we rest

there for the evening, sir?

THE COMMISSIONER: Yes, until 10 o'clock tomorrow morning then.

Whereupon the Hearing was adjourned at 4:40 until Thursday, October 13th, 1983, at 10:00 a.m.



